

**FINAL REPORT**

Study Title

Oral (Drinking Water) Developmental Toxicity Study  
of Ammonium Perchlorate in Rats

Data Requirement

U.S. Environmental Protection Agency  
Pesticide Assessment Guidelines  
Subdivision F, 83-3

Author

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4 August 2000  
(Final Report)

Performing Laboratory

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Laboratory Project ID

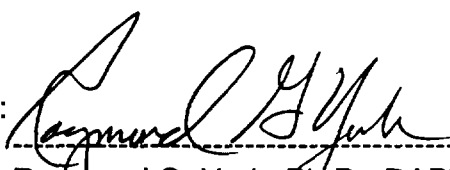
Argus Research Laboratories, Inc., Protocol Number: 1416-003D

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## GOOD LABORATORY PRACTICE STATEMENT

This study was conducted according to U.S. Environmental Protection Agency (EPA TSCA) "Good Laboratory Practice Standards; Final Rule" (40 CFR Part 792). Any areas of noncompliance are documented in the study record. No deviations existed that significantly affected the validity of the study.

Study Director:

 04 AUG 00  
Raymond G. York, Ph.D., DABT      Date  
Argus Research Laboratories, Inc.

Sponsor:

\_\_\_\_\_  
Perchlorate Study Group\_\_\_\_\_  
Date

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Protocol 1416-003: Oral (Drinking Water) Developmental Toxicity Study of  
Ammonium Perchlorate in Rats

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**TITLE: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY  
OF AMMONIUM PERCHLORATE IN RATS**

**ARGUS RESEARCH LABORATORIES, INC., PROTOCOL  
NUMBER: 1416-003**

**I. SUMMARY AND CONCLUSION**

**A. Methods<sup>a</sup>**

One hundred -twenty presumed pregnant CrI:CD®(SD)IGS BR VAF/Plus® female rats were randomly assigned to five exposure groups (Groups I through V). Twenty rats per group were selected for Caesarean-sectioning. The test substance was ammonium perchlorate, 99.8%, and the carrier was reverse osmosis membrane processed deionized water. A constant concentration (%) of the test substance equivalent to target doses, 0 (Carrier), 0.01, 0.1, 1.0 and 30.0 mg/kg/day, was offered to the rats in the drinking water, beginning 15 days before cohabitation and continuing through the day of sacrifice.

The rats were observed for viability at least twice each day of the study. The rats were examined daily during the exposure period for clinical observations of effects of the test substance, abortions, premature deliveries and deaths. Body weights were recorded twice during acclimation, and daily throughout the exposure period. Feed and water consumption values were recorded daily throughout the exposure period.

All rats were sacrificed on day 21 of presumed gestation (DG 21), and a gross necropsy of the thoracic, abdominal and pelvic viscera was performed. Gravid uterine weights were recorded. The number of corpora lutea in each ovary was recorded. The uterus of each rat was excised and examined for pregnancy, number and distribution of implantations, live and dead fetuses and early and late resorptions. Placentae were examined for abnormalities (size, color or shape). Each fetus was identified, weighed and examined for sex and gross external alterations. Approximately one-half of the fetuses in each litter were examined for soft tissue alterations. The heads of these fetuses were examined

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- a. Detailed descriptions of all procedures used in the conduct of this study are provided in the appropriate sections of this report and in APPENDIX C (PROTOCOL AND AMENDMENTS).

by free-hand sectioning. The remaining fetuses in each litter were examined for skeletal alterations and cartilage development.

## **B. Results**

The average actual consumed daily dosages during the prehabitation exposure period were 0.00, 0.01, 0.08, 0.70 and 21.69 mg/kg/day and during the gestation exposure period were 0.00, 0.01, 0.10, 0.96 and 28.27 mg/kg/day for the 0 (Carrier), 0.01, 0.1, 1.0 and 30.0 mg/kg/day target dosage groups, respectively.

There were no deaths during the pre-mating or gestation periods; all rats survived to scheduled sacrifice. All clinical and necropsy observations were considered unrelated to the test substance because: 1) the incidences were not dosage-dependent; and/or 2) the observations are commonly seen in rats in the laboratory environment.

Body weights, body weight changes and gravid uterine weights were comparable among the five exposure groups during the prehabitation and gestation periods. Any significant reductions were transient and not considered treatment-related because they were not dosage-dependent.

Absolute and relative water consumption values were comparable among the five exposure groups during the prehabitation and gestation periods. Any significant differences in water consumption values were not considered test substance-related because they were not dosage-dependent.

Average absolute and relative feed consumption values during the prehabitation and gestation periods were comparable among the five exposure groups. Any significant differences in feed consumption values were not considered treatment-related because they were not dosage-dependent.

Caesarean-sectioning observations were based on 19, 19, 17, 20 and 20 pregnant rats with one or more live fetuses on DG 21 in Groups I through V, respectively. Caesarean-sectioning and litter parameters were unaffected by exposure to the test substance as high as 30.0 mg/kg/day. The litter averages for corpora lutea, implantations, dead fetuses, early and late resorptions, percent resorbed conceptuses, percent male fetuses and fetal body weights were comparable among the five exposure groups. There were no dead fetuses and no dams had a litter consisting of only resorbed conceptuses. All placentae appeared normal.

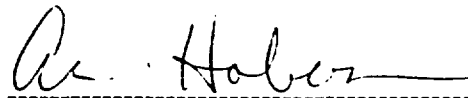
Fetal evaluations were based on 316, 271, 236, 325 and 282 DG 21 Caesarean-delivered live fetuses in 19, 19, 17, 20 and 20 litters in the five respective exposure groups. The average number of ossification sites per litter for sternal centers and for forelimb phalanges were significantly reduced in the

30.0 mg/kg/day exposure group. These reductions were considered reversible developmental delays.

No fetal alterations were attributable to exposures of the test substance as high as 30.0 mg/kg/day because: 1) the incidences were not dosage-dependent; 2) the observation occurred in only one or two high exposure group fetuses; and/or 3) the incidences were within the averages observed historically at the Testing Facility.

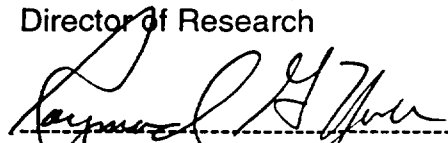
**C. Conclusion**

Based on these data, the maternal no-observable-adverse-effect-level (NOAEL) for ammonium perchlorate is greater than 30.0 mg/kg/day. Exposures as high as 30.0 mg/kg/day did not have an effect on the incidence of adverse clinical or necropsy observations, body weights, uterine weights, body weight change nor feed or water consumption values. The developmental NOAEL is also greater than 30.0 mg/kg/day. There were no adverse effects on embryo-fetal development as evaluated in this study, and based on these data, ammonium perchlorate should not be identified as a developmental toxicant.

 4-AUG-00

Alan M. Hoberman, Ph.D., DABT  
Director of Research

Date

 04 AUG 00

Raymond G. York, Ph.D., DABT  
Associate Director of Research and  
Study Director

Date

## **II. DESCRIPTION OF TEST PROCEDURES**

The final report for this study was issued as two stand-alone GLP compliant reports. This report describes the results of Part D of the study, during which standard prenatal developmental toxicity endpoints in maternal rats and fetuses were evaluated (OPPTS 870.3700).

### **A. Conduct of Study**

#### **A.1. Sponsor**

Perchlorate Study Group, Highway 50 & Aerojet Road, Building 20019/  
Department 0330, Rancho Cordova, California 95670

#### **A.2. Testing Facility**

Argus Research Laboratories, Inc., 905 Sheehy Drive, Building A, Horsham,  
Pennsylvania 19044-1297

#### **A.3. Study Number**

1416-003

#### **A.4. Purpose of the Study**

The purpose of Part D of this study was to determine the teratogenicity of perchlorate in a second species (rat).

Data from this study will be used in developing the final Reference Dose (RfD) for perchlorate, needed by the U.S. Environmental Protection Agency for risk assessment and to establish cleanup levels of perchlorate-contaminated sites.

#### **A.5. Study Design**

The requirements of the U.S. Environmental Protection Agency<sup>(1)</sup> were used as the basis for study design.

#### **A.6. Regulatory Compliance**

The study was conducted in compliance with Good Laboratory Practice (GLP) regulations of the U.S. Environmental Protection Agency (EPA)<sup>(2)</sup>. There were no deviations from the GLP regulations that affected the quality or integrity of the study. Quality Assurance Unit findings derived from the inspections during the conduct of this study are documented and have been provided to the Study Director and the Testing Facility Management.

**A.7. Ownership of the Study**

The Sponsor owns the study. All raw data, analyses, reports and preserved tissues are the property of the Sponsor.

**A.8. Study Monitor**

Michael F. Girard (Perchlorate Study Group Representative)

**A.9. Scientific Advisor**

Michael L. Dourson, Ph.D., DABT [Toxicology Excellence for Risk Assessment (TERA), Cincinnati, Ohio]

**A.10. Study Director**

Raymond G. York, Ph.D., DABT (Associate Director of Research)

**A.11. Technical Performance**

John F. Barnett, B.S. (Director of Laboratory Operations)  
Christopher Carboni (Team Leader - General Laboratory)  
Sharon Adamski, B.S. (Laboratory Technician)  
Theodore J. Detwiler, B.S. (Laboratory Technician)  
Brian K. Kelsch (Necropsy Laboratory Technician)  
Michael D. Brennan, B.S. (Formulation Laboratory Technician)

**A.12. Report Preparation**

Raymond G. York, Ph.D., DABT  
Jo Ann Frazee, M.S. (Study Coordinator)  
Valerie A. Sharper, M.S. (Director of Study Management)  
Elizabeth M. Wiley, B.S. (Data Management Specialist)  
Georgia Y. Burnett, A.A.S. (Report Administrator)

**A.13. Report Review**

Alan M. Hoberman, Ph.D., DABT (Director of Research)  
Mildred S. Christian, Ph.D., Fellow, ATS (Executive Director of Research)

**A.14. Date Protocol Signed**

27 December 1999

**A.15. Dates of Technical Performance**

Rat Arrival	25 JAN 00
Exposure Period (15 days prior to cohabitation and continuing through sacrifice <sup>a</sup> )	31 JAN 00 - 15 MAR 00
Cohabitation Period	14 FEB 00 PM - 23 FEB 00 AM
Day 0 of Presumed Gestation (DG 0)	15 FEB 00 - 23 FEB 00
Caesarean-Sectioning Period (DG 21)	07 MAR 00 - 15 MAR 00

**A.16. Records Maintained**

The original report, raw data and reserve samples of the bulk test substance and carrier are retained in the archives of Argus Research Laboratories, Inc. Any preserved tissues are retained in the archives of the Testing Facility for one year after the mailing of the draft final report, after which time the Sponsor will decide their final disposition. All unused bulk test substance and prepared formulations were discarded at the Testing Facility.

**B. Test Substance Information****B.1. Description**

Ammonium Perchlorate, 99.8% (CAS Number 7790-98-9) - a white, crystalline solid

**B.2. Lot Number**

03907LF

**B.3. Date Received and Storage Conditions**

The test substance was received on 12 January 1998, from Aldrich Chemical Company, Milwaukee, Wisconsin, and stored at room temperature.

**B.4. Special Handling Instructions**

Protective clothing, gloves, half-face respirator, safety goggles or safety glasses and a face-shield were worn when handling the bulk test substance and prepared solutions. The formulations were prepared in a fume hood.

- 
- a. The rats were given the test substance until the day of sacrifice rather than allowing access until the day before sacrifice. This deviation did not affect the outcome or interpretation of the study because the regulatory guidelines allow exposure up to the day of sacrifice.

**B.5. Analysis of Purity**

The Certificate of Analysis for the test substance is available in APPENDIX D.

**C. Carrier Information****C.1. Description**

Reverse osmosis membrane processed deionized water (R.O. deionized water)

**C.2. Storage Conditions**

The R.O. deionized water is available from a continuous source at the Testing Facility and is maintained at room temperature.

**C.3. Special Handling Instructions**

Standard safety precautions (use of protective clothing, gloves, dust-mist respirator, safety goggles or safety glasses and a face-shield) were taken when handling the carrier.

**C.4. Analysis of Purity**

Neither the Sponsor nor the Study Director was aware of any potential contaminants likely to have been present in the carrier that would interfere with the results of this study. Results of the R.O. deionized water analyses are available in APPENDIX E.

**D. Test Substance Preparation**

Formulations of ammonium perchlorate were prepared at least once weekly at the Testing Facility. Prepared stock formulations (10 mg/mL) were stored refrigerated. Dosage solutions were stored at room temperature.

**D.1. Sample Information**

Sample Type	Size	Date Retained	Storage/Shipping Conditions	Shipped To	Date Shipped
Concentration <sup>a</sup> (all levels)	2 mL	27 DEC 99 06 MAR 00	Refrigerated	Air Force Research Laboratory <sup>b</sup>	27 DEC 99 06 MAR 00
Bulk Test Substance Reserve	5 g 1 g	27 DEC 99 15 MAR 00	Room temperature	Testing Facility Archives	17 APR 00 17 APR 00
Carrier Reserve	5 mL	27 DEC 99	Room temperature	Testing Facility Archives	17 APR 00

- a. Triplicate samples were taken from each formulation (including stock solution and carrier) on the first and last days prepared. Two samples from each triplicate set were shipped for analysis; the remaining samples were retained at the Testing Facility as backup samples.
- b. Operational Toxicology Branch, Air Force Research Laboratory (AFRL), Wright Patterson Air Force Base, Ohio.

**D.2. Analytical Results**

Documentation of the stability of the prepared solutions is available in APPENDIX F. Stability has been established for up to 109 days. Results of the concentration analysis are listed in the chart and available in APPENDIX F.

Actual concentrations of the test substance formulations:

Target Dosage (mg/kg/day)	0	0.01	0.1	1.0	30.0
Concentration ( $\mu\text{g/mL}$ )	0	0.08	0.8	7.6	227.4
First Preparation ( $\mu\text{g/mL}$ )	0	0.07	0.7	6.6	197.6
Last Preparation ( $\mu\text{g/mL}$ )	0	0.07	0.6	6.9	218.4

**E. Test System****E.1. Species**

Rat

**E.2. Strain**

CrI:CD®(SD)IGS BR VAF/Plus®



**E.3. Supplier (Source)**

Charles River Laboratories, Inc., St. Constant, Quebec, CANADA

**E.4. Sex**

Female (Note: Male rats were used only for the purposes of breeding and are not considered part of the Test System. Breeder male rats were exposed to the test substance during the cohabitation period, and were sacrificed upon completion of the cohabitation period.)

**E.5. Rationale for Test System**

The CrI:CD®(SD)IGS BR VAF/Plus® rat was selected as the Test System because: 1) this strain of rat has been demonstrated to be sensitive to reproductive and developmental toxins and has been widely used throughout industry for reproductive and developmental toxicity evaluations; and 2) historical data and experience exist at the Testing Facility<sup>(3-5)</sup>.

**E.6. Test System Data**

Number of Rats	140
Approximate Date of Birth	28 NOV 99
Approximate Age at Arrival	59 days
Weight (g) on Day After Arrival	185 - 230
Weight (g) at Study Assignment	213 - 237

**E.7. Breeder Male Rats**

	<u>Shipment 1</u>	<u>Shipment 2</u>
Number of Rats	100	300
Approximate Date of Birth	13 SEP 99	24 OCT 99
Approximate Age at Arrival	72 days	73 days
Weight (g) on Day After Arrival	296 - 341	279 - 364
Weight (g) at Cohabitation	543 - 726	450 - 598

**E.8. Method of Randomization**

Upon arrival, male and female rats were assigned to individual housing on the basis of computer-generated random units. After acclimation, rats were selected for study on the basis of physical appearance and body weight. The rats were assigned to groups based on computer-generated (weight-ordered) randomization procedures. Twenty female rats per group were selected for Caesarean-sectioning. Gestation data for rats not selected for Caesarean-sectioning were not tabulated and are retained in the raw data records.

**E.9. System of Identification**

Male rats were given unique permanent identification numbers upon assignment to the Testing Facility's breeder male rat population. Female rats were assigned temporary numbers at receipt and given unique permanent identification numbers when assigned to the study. Each rat was individually identified with a Monel® self-piercing ear tag (Gey Band and Tag Co., Inc., No. MSPT 20101) inscribed with the rat's designated unique permanent number. Cage tags were marked with the study number, permanent rat number, sex, test substance identification and dosage level.

**F. Husbandry****F.1. Research Facility Registration**

USDA Registration No. 23-R-099 under the Animal Welfare Act, 7 U.S.C. 2131 *et seq.*

**F.2. Study Rooms**

The study rooms were maintained under conditions of positive airflow relative to a hallway and independently supplied with a minimum of ten changes per hour of 100% fresh air that had been passed through 99.97% HEPA filters. Room temperature and humidity were monitored constantly throughout the study. Room temperature was targeted at 64°F to 79°F (18°C to 26°C); relative humidity was targeted at 30% to 70%, see APPENDIX E (ENVIRONMENTAL AND HUSBANDRY REPORTS).

**F.3. Housing**

All rats were individually housed in stainless steel, wire-bottomed cages except during the cohabitation period. During cohabitation, each pair of male and female rats was housed in the male rat's cage. All cage sizes and housing conditions were in compliance with the *Guide for the Care and Use of Laboratory Animals*<sup>(6)</sup>.

**F.4. Lighting**

An automatically-controlled fluorescent light cycle was maintained at 12-hours light:12-hours dark, with each dark period beginning at 1900 hours EST.

**F.5. Sanitization**

Cage pan liners were changed approximately three times each week. Cages were changed approximately every other week.

**F.6. Feed**

Rats were given *ad libitum* access to Certified Rodent Diet® #5002 (PMI Nutrition International, St. Louis, Missouri) in individual feeders.

**F.7. Feed Analysis**

Analyses were routinely performed by the feed supplier. No contaminants at levels exceeding the maximum concentration limits for certified feed or deviations from expected nutritional requirements were detected by these analyses. Copies of the results of the feed analyses are available in the raw data and APPENDIX E.

Neither the Study Director nor the Sponsor was aware of any potential contaminants likely to have been present in the feed that would have interfered with the results of this study.

**F.8. Water**

All water was from a local source and was processed by passage through a reverse osmosis membrane and additional deionizing cartridges (R.O. deionized water) before use. Chlorine was not added to the processed water.

During the acclimation period, rats were given R.O. deionized water available *ad libitum* from individual amber bottles attached to the cages. During the exposure period, rats were given either R.O. deionized water only (carrier control group) or test drinking water prepared using R.O. deionized water and the test substance. These were available *ad libitum* from individual amber bottles attached to the cages.

**F.9. Water Analysis**

The processed water is analyzed twice annually for possible chemical contamination (Lancaster Laboratories, Lancaster, Pennsylvania) and monthly for possible bacterial contamination (Analytical Laboratories, Inc., Chalfont, Pennsylvania). Copies of the results of the water analyses are available in the raw data and in APPENDIX E.

Neither the Study Director nor the Sponsor was aware of any potential contaminants likely to have been present in the water that would have interfered with the results of this study.

## G. Methods

### G.1. Dosage Administration

Dosage Group	Target Dosage (mg/kg/day)	Number of Female Rats <sup>a</sup>	Assigned Numbers
I	0 (Carrier)	24	19101 - 19124
II	0.01	24	19125 - 19148
III	0.1	24	19149 - 19172
IV	1.0	24	19173 - 19196
V	30.0	24	19197 - 19220

- a. Twenty-four rats were initially assigned to each exposure group, rather than 23. This deviation did not affect the outcome or interpretation of the study because the number of rats selected for evaluation at Caesarean-sectioning (20) did not change.

Initial test substance concentrations were calculated to deliver the target dosage based on average water consumption of 33 mL/rat/day (132 mL/kg/day) for a 250 g rat. Concentrations were adjusted based on actual water consumption and body weights recorded the previous week<sup>a</sup>. The test substance was considered 100% pure for the purpose of dosage calculations. The actual test substance concentrations offered to the rats were as follows:

Preparation Date	Dosage Group Concentration (µg/mL)			
	Group II	Group III	Group IV	Group V
28 JAN 00	0.0658	0.658	6.58	197.27
03 FEB 00	0.0658	0.658	6.58	197.27
14 FEB 00	0.0633	0.630	6.28	193.50
21 FEB 00	0.0732	0.733	7.41	237.06
28 FEB 00	0.0673	0.739	7.28	242.42
06 MAR 00	0.0665	0.623	6.78	218.50

- a. On 14 February 2000, the average water consumption was taken from the historical control data of female rats of comparable weight, rather than from the summaries based on water consumption data from the previous week because the latter data was not available at the time of test substance preparation. This deviation did not affect the outcome or interpretation of the study because the historical control data was from the same test substance, concentrations and source of rats.

**G.2. Rationale for Dosage Selection**

Target dosage levels were selected by the Sponsor based on previous studies conducted with the test substance. The 10 mg/kg/day dosage resulted in thyroid effects in pups on day 5 postpartum in a neurobehavioral developmental study (Argus Research Laboratories, Inc., Protocol 1613-002), and was clearly an effect level in a 90-day drinking water study in rats<sup>(7)</sup>.

Because the dosage in the neurobehavioral developmental study did not begin until after mating (confirmation of pregnancy), exposure started two weeks prior to the start of cohabitation to ensure a hypothyroid state, and continued until sacrifice.

**G.3. Route of Administration**

Oral (drinking water)

**G.4. Rationale for Route of Administration**

The oral (drinking water) route was selected because it is the most likely route of human exposure.

**G.5. Frequency of Administration**

A constant concentration (%) of the test substance equivalent to target doses was offered to the rats in the drinking water daily. Concentrations were adjusted weekly as necessary, based on actual body weight and water consumption values recorded the previous week, except as previously noted. Rats were given continual access to the test substance in the drinking water beginning 15 days before cohabitation and continuing through the day of sacrifice.

**G.6. Method of Study Performance**

The female rats were observed for viability at least twice each day of the study and for general appearance twice during acclimation. The rats were examined daily during the exposure period for clinical observations of effects of the test substance, abortions, premature deliveries and deaths. Body weights were recorded twice during acclimation, and daily throughout the exposure period. Feed and water consumption values were recorded daily throughout the exposure period.

Following approximately two weeks of exposure to the test substance or carrier, the female rats were cohabited with breeder male rats, one male rat per female rat. The cohabitation period consisted of a maximum of nine days. Female rats with spermatozoa observed in a smear of the vaginal contents and/or a copulatory plug observed *in situ* were considered to be at DG 0 and assigned to individual housing.

### **G.7. Gross Necropsy**

All rats were sacrificed by carbon dioxide asphyxiation on DG 21, and a gross necropsy of the thoracic, abdominal and pelvic viscera was performed. To confirm the pregnancy status, uteri from rats that appeared nonpregnant were examined while being pressed between glass plates. Gravid uterine weights were recorded. Tissues with gross lesions were preserved in neutral buffered 10% formalin for possible future evaluation; all other maternal tissues were discarded. Representative photographs of maternal lesions are available in the raw data.

The number of corpora lutea in each ovary was recorded<sup>a</sup>. The uterus of each rat was excised and examined for pregnancy, number and distribution of implantations, live and dead fetuses and early and late resorptions. An early resorption was defined as one in which organogenesis was not grossly evident. A late resorption was defined as one in which the occurrence of organogenesis was grossly evident. A live fetus was defined as a term fetus that responded to mechanical stimuli. Nonresponding term fetuses are considered to be dead (there were no dead fetuses). Dead fetuses and late resorptions are differentiated by the degree of autolysis present; marked to extreme autolysis indicated that the fetus was a late resorption. Placentae were examined for abnormalities (size, color or shape).

Each fetus was removed from the uterus, placed in an individual container and identified with a tag noting the study number, litter number, uterine distribution and fixative. Each fetus was subsequently weighed and examined for sex and gross external alterations. Live fetuses were sacrificed by an intraperitoneal injection of Beuthanasia®-D Special (Schering-Plough Animal Health).

Approximately one-half of the fetuses in each litter were examined for soft tissue alterations using a variation of the microdissection technique of Staples<sup>(8)</sup>. The heads of these fetuses were fixed in Bouin's solution and subsequently examined by free-hand sectioning; sections were stored in alcohol. The remaining fetuses in each litter were eviscerated, cleared, stained with alizarin red S<sup>(9)</sup> and examined for skeletal alterations and cartilage development. Skeletal preparations were retained in glycerin with thymol added as a preservative. Photographs of fetal alterations are available in the raw data.

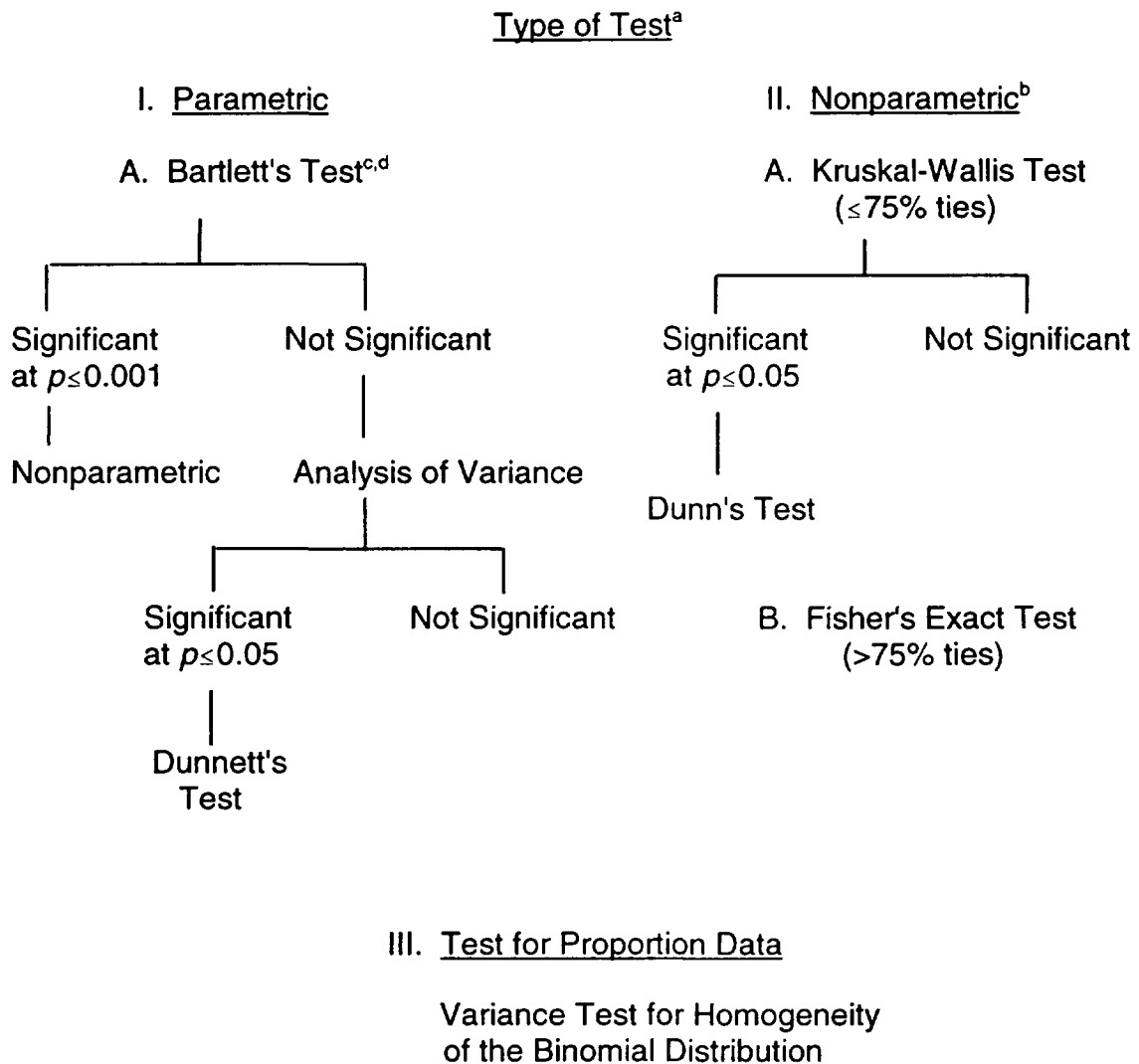
Rats not selected for Caesarean-sectioning were sacrificed at the completion of the cohabitation period (rats without a confirmed mating date) or on DG 21 and were discarded without further evaluation.

- 
- a. The number of corpora lutea were recorded incorrectly for rat 19139 in the 0.01 mg/kg/day dosage group. This deviation did not affect the outcome or interpretation of the study because sufficient data were collected to evaluate this parameter.

**G.8. Data Acquisition and Statistical Analysis**

Data generated during the course of this study were recorded either by hand or using the *Primedica Argus Automated Data Collection and Management System* and the *Vivarium Temperature and Relative Humidity Monitoring System*. All data were tabulated, summarized and statistically analyzed using the *Primedica Argus Automated Data Collection and Management System*, the *Vivarium Temperature and Relative Humidity Monitoring System*, *Microsoft Excel* [part of Microsoft Office 97 (version SR-2)] and/or *The SAS System* (version 6.12).

The following schematic represents the statistical analyses of data:



- 
- a. Statistically significant probabilities are reported as either  $p \leq 0.05$  or  $p \leq 0.01$ .
  - b. Proportion data are not included in this category.
  - c. Used only to analyze data with homogeneity of variance.
  - d. Test for homogeneity of variance.



Clinical observations and other proportion data were analyzed using the Variance Test for Homogeneity of the Binomial Distribution<sup>(10)</sup>.

Continuous data (e.g., maternal body weights, body weight changes, feed and water consumption values and litter averages for percent male fetuses, percent resorbed conceptuses, fetal body weights, fetal anomaly data and fetal ossification site data) were analyzed using Bartlett's Test of Homogeneity of Variances<sup>(11)</sup> and the Analysis of Variance<sup>(12)</sup>, when appropriate [i.e., Bartlett's Test was not significant ( $p > 0.05$ )]. If the Analysis of Variance was significant ( $p \leq 0.05$ ), Dunnett's Test<sup>(13)</sup> was used to identify the statistical significance of the individual groups. If the Analysis of Variance was not appropriate [i.e., Bartlett's Test was significant ( $p \leq 0.05$ )], the Kruskal-Wallis Test<sup>(14)</sup> was used, when 75% or fewer ties were present; when more than 75% ties were present, Fisher's Exact Test<sup>(15)</sup> was used. In cases where the Kruskal-Wallis Test was statistically significant ( $p \leq 0.05$ ), Dunn's Method of Multiple Comparisons<sup>(16)</sup> was used to identify the statistical significance of the individual groups.

Count data obtained at Cesarean-sectioning of the dams were evaluated using the procedures described above for the Kruskal-Wallis Test<sup>(14)</sup>.

### **III. RESULTS**

#### **A. Consumed Dosages (Summaries - Tables B1 and B2)**

The average actual consumed daily dosages for the female rats during the precohabitation exposure period (calculated as days 1 to 15 of the study) were 0.00, 0.01, 0.08, 0.70 and 21.69 mg/kg/day for the 0 (Carrier), 0.01, 0.1, 1.0 and 30.0 mg/kg/day target dosage groups, respectively.

The average actual consumed daily dosages for the female rats for the gestation exposure period (calculated as gestation days 0 to 21) were 0.00, 0.01, 0.10, 0.96 and 28.27 mg/kg/day for the 0 (Carrier), 0.01, 0.1, 1.0 and 30.0 mg/kg/day target dosage groups, respectively.

#### **B. Mortality, Clinical and Necropsy Observations (Summaries - Tables B3 and B4; Individual Data - Tables B24 and B25)**

##### **B.1. Mortality**

There were no deaths during the premating or gestational periods; all rats survived to scheduled sacrifice.

##### **B.2. Clinical Observations**

All clinical observations were considered unrelated to the test substance because: 1) the incidences were not dosage-dependent; and/or 2) the observations are commonly seen in rats in the laboratory environment. These observations included localized alopecia (limbs), right ear torn and red perivaginal substance. Localized alopecia on the limbs was significantly increased ( $p \leq 0.05$ ) in the 30.0 mg/kg/day exposure group during the gestation period, compared to the carrier group. This significant increase was not considered test substance-related because this observation is commonly observed in rats in the laboratory environment.

##### **B.3. Necropsy Observations**

One rat in the 1.0 mg/kg/day exposure group had a red substance in the stomach. This observation was not considered test substance-related because it was not dosage-dependent.

#### **C. Body Weights, Gravid Uterine Weights and Body Weight Changes (Figure 1; Summaries - Tables B5 through B8; Individual Data - Tables B26 and B27)**

Body weights and body weight changes were comparable among the five exposure groups during the precohabitation and gestation periods. Body weights during the gestation period were significantly reduced ( $p \leq 0.05$ ) in the

0.01 mg/kg/day exposure group on DGs 5, 18 and 19 and in the 0.1 mg/kg/day exposure group on DGs 0, 1, 2 and 5, as compared to the carrier group values. These significant reductions were transient and not considered treatment-related because they were not dosage-dependent.

Corrected body weight changes (DG 21 maternal body weight minus the gravid uterine weight) were significantly increased ( $p \leq 0.05$ ) in the 0.1 and 30.0 mg/kg/day exposure groups. These significant increases were not considered treatment-related because: 1) they were not exposure-dependent; and 2) they were a single event at each exposure level. Absolute gravid uterine was comparable among the five exposure groups and did not differ significantly.

**D. Absolute (g/day) and Relative (g/kg/day) Water Consumption Values (Summaries - Tables B9 through B12; Individual Data - Tables B28 and B29)**

Absolute (g/day) and relative (g/kg/day) water consumption values were comparable among the five exposure groups during the prehabitation and gestation periods. Relative water consumption values was significantly increased ( $p \leq 0.05$  to  $p \leq 0.01$ ) in the 0.01 mg/kg/day exposure group on DGs 18 to 21 and in the 0.1 mg/kg/day exposure group on DGs 12 to 15. These significant increases were not considered treatment-related because: 1) they were not exposure-dependent; and 2) they were a single event at each exposure level.

**E. Absolute (g/day) and Relative (g/kg/day) Feed Consumption Values (Summaries - Tables B13 through B16; Individual Data - Tables B30 and B31)**

Average absolute (g/day) and relative (g/kg/day) feed consumption values for female rats during the prehabitation and gestation periods were comparable among the five exposure groups. Absolute feed consumption values in the 0.01 and 0.1 mg/kg/day exposure groups were significantly reduced ( $p \leq 0.05$ ) on DGs 0 to 6. These significant reduction were not considered treatment-related because they were not dosage-dependent.

**F. Caesarean-Sectioning and Litter Observations (Summaries - Tables B17 and B18; Individual Data - Table B32 through B34)**

There were 19, 19, 17, 20 and 20 rats pregnant and Caesarean-sectioned on DG 21 in the five respective exposure groups.

Caesarean-sectioning and litter parameters were unaffected by exposure to the test substance as high as 30.0 mg/kg/day. The litter averages for corpora lutea, implantations, dead fetuses, early and late resorptions, percent resorbed conceptuses and percent male fetuses were comparable among the five

exposure groups. There were no dead fetuses and no dams had a litter consisting of only resorbed conceptuses. All placentae appeared normal.

The average litter size and the average number of live fetuses were significantly reduced ( $p \leq 0.05$ ) in the 30.0 mg/kg/day exposure group. These reductions were not considered treatment-related because: 1) the value was within the ranges observed historically at the Testing Facility<sup>a</sup>; and 2) the value was not toxicologically important because there was no significant increase in fetal deaths or resorptions nor significant reduction in number of implantations.

The average litter weight of the male fetuses was significantly increased ( $p \leq 0.05$ ) in the 0.1 and 1.0 mg/kg/day exposure groups, compared to the carrier group values. These significant increases were not considered treatment-related because they were not exposure-dependent.

**G. Fetal Alterations (Summaries - Tables B19 through B23; Individual Data - Table B35)**

Fetal alterations were defined as: 1) malformations (irreversible changes that spontaneously occur at low incidences in this species and strain); and 2) variations (common findings in this species and strain, and reversible delays or accelerations in development). Litter averages were calculated for specific fetal ossification sites as part of the evaluation of the degree of fetal ossification.

Fetal evaluations were based on 316, 271, 236, 325 and 282 DG 21 Cesarean-delivered live fetuses in 19, 19, 17, 20 and 20 litters in the five respective exposure groups. Each fetus was examined for gross external alterations. Of these respective fetuses, 153, 131, 112, 158 and 137 fetuses were examined for soft tissue alterations, and 163, 140, 124, 167 and 145 fetuses were examined for skeletal alterations and fetal ossification site averages. No fetal alterations were attributable to exposures of the test substance as high as 30.0 mg/kg/day.

**G.1. Summary of Fetal Alterations (Summary - Table B19; Individual Data - Table B35)**

In Groups I through V, litters with fetuses with alterations numbered 7 (36.8%), 4 (21.0%), 8 (47.0%), 4 (20.0%) and 4 (20.0%), respectively. The numbers of fetuses with any alteration observed were 8 (2.5%), 4 (1.5%), 12 (5.1%)<sup>\*\*</sup>, 5 (1.5%) and 5 (1.8%) and the percentages of fetuses with any alteration per litter were 2.6, 1.3, 5.2, 1.5 and 1.9, in these same respective exposure groups.

All fetal alterations in this study are described in the following information.

- 
- a. See APPENDIX G (HISTORICAL CONTROL DATA).  
 \*\* Significantly different from the carrier group value ( $p \leq 0.01$ ).

**G.2. Fetal Gross External Alterations (Summary - Table B20; Individual Data - Table B35)**

One 0.01 mg/kg/day exposure group fetus (19144-9) had a lateral right cleft snout and a unilateral right cleft palate. Skeletal examination of this fetus revealed an incompletely ossified maxillae and right palate, an incompletely ossified 1st sternal centra and a bifid centrum of the 13th thoracic vertebrae.

**G.3. Fetal Soft Tissue Alterations (Summary - Table B21; Individual Data - Table B35)****G.3.a. Malformations**

One carrier group fetus (19114-12) had a bifurcated aortic arch and an absent innominate vessel.

**G.3.b. Variations****G.3.b.1. Vessels**

Absence of the innominate vessel occurred in 2 (19103-16; 19114-12), 0, 3 (19150-6; 19161-17; 19167-2), 1 (19187-14) and 0 fetuses in 2, 0, 3, 1 and 0 litters in the five respective exposure groups. Carrier group fetus 19114-12 had a bifurcated aortic arch, as previously described. No additional alterations occurred in these fetuses.

The umbilical artery descended to the left of the urinary bladder of one carrier group fetus (19103-4) as the only alteration.

**G.3.b.2. Ureters**

Distended (slight) right ureter occurred in one 0.01 mg/kg/day exposure group fetus (19135-6) as the only alteration.

**G.4. Fetal Skeletal Alterations (Summaries - Tables B22 and B23; Individual Data - Table B35)****G.4.a. Malformations**

There were no malformations observed at skeletal evaluation.

**G.4.b. Variations****G.4.b.1. Skull**

Incomplete ossification of the maxillae and palate occurred in one externally malformed 0.01 mg/kg/day exposure group fetus, as previously described. This

fetus also had incompletely ossified 1st sternal centra and a bifid centrum of the 13th thoracic vertebrae.

#### **G.4.b.2. Vertebrae**

A bifid centrum of the 11th, 12th or 13th thoracic vertebrae occurred in 0, 1, 2, 3 and 0 fetuses from 0, 1, 1, 2 and 0 litters in the 0, 0.01, 0.1, 1.0 and 30.0 mg/kg/day exposure groups, respectively. Fetus 19144-9 in the 0.01 exposure group had additional gross and skeletal alterations, as previously described.

#### **G.4.b.3. Ribs**

A cervical rib was present at the 7th cervical vertebra in 4, 2, 5, 1 and 1 fetuses from 4, 2, 4, 1 and 1 litters in the five respective exposure groups. These fetuses had no additional alterations.

Wavy ribs occurred in two 30.0 mg/kg/day exposure group littermates (19208-5,-15). Fetus 19208-5 also had incompletely ossified (hypoplastic) right 9th and 10th ribs. No additional findings occurred in these fetuses.

#### **G.4.b.4. Sternum**

Incompletely ossified, asymmetric and fused sternal centra occurred in 1, 1, 1, 0 and 1 fetuses from 1, 1, 1, 0 and 1 litters in the 0 (Carrier), 0.01, 0.1, 1.0 and 30.0 mg/kg/day exposure groups, respectively.

Incompletely ossified 1st sternal centra occurred in one fetus in each of the 0.01, 0.1 and 30.0 mg/kg/day exposure groups (19144-9; 19150-1; 19206-8). Fetus 19144-9 had additional alterations described previously. Fetus 19150-1 also had not ossified pubis.

Asymmetric 1st through 3rd sternal centra and fused 1st and 2nd sternal centra occurred in one carrier group fetus (19113-3).

#### **G.4.b.5. Pelvis**

Not ossified pubes, incompletely ossified pubes and ischia occurred in 2 and 1 fetuses from 2 and 1 litters in the 0.1 and 30.0 mg/kg/day exposure groups, respectively.

Not ossified pubes occurred in one fetus in each of the 0.1 and 30.0 mg/kg/day exposure groups (19150-1 and 19202-7, respectively). Fetus 19150-1 had additional alterations as described previously.

Incompletely ossified pelvic pubis and ischium occurred in one 0.1 mg/kg/day exposure group fetus (19164-7). This fetus had no additional alterations.

**G.4.c. Fetal Ossification Site Averages**

The average number of ossification sites in the hyoid, vertebrae (cervical, thoracic, lumbar, sacral and caudal), ribs, sternum (manubrium and xiphoid), forelimbs (carpals and metacarpals) and hindlimbs (tarsals, metatarsals and phalanges) occurred at similar incidences in all exposure groups and did not significantly differ. The average number of ossification sites per litter for sternal centers and for forelimb phalanges were significantly reduced ( $p \leq 0.05$  or  $p \leq 0.01$ ) in the 30.0 mg/kg/day exposure group. These reductions were considered reversible developmental delays and were not considered toxicologically important because there were no skeletal malformations of the sternum or phalanges at this exposure level.

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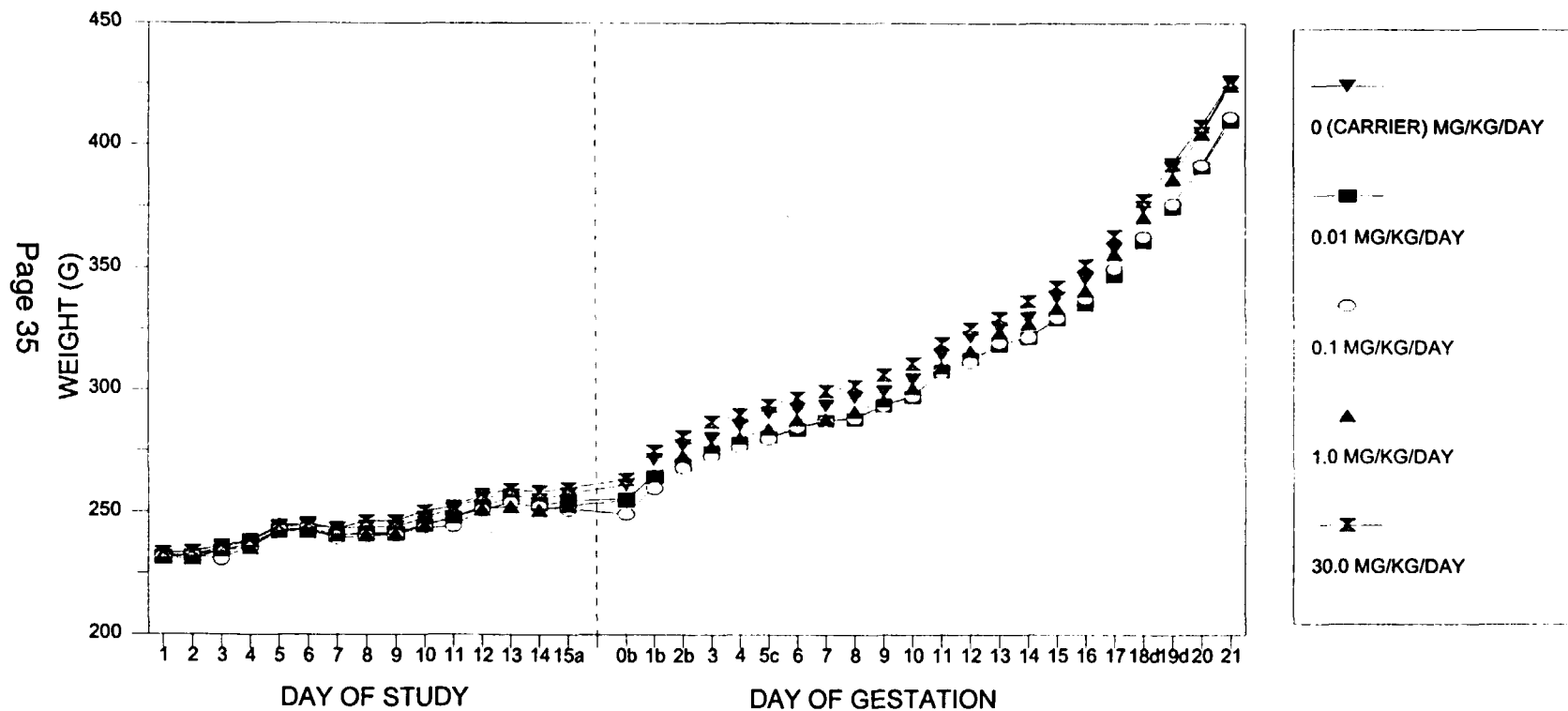
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APPENDIX A  
REPORT FIGURE

## BODY WEIGHTS

### PART D

Figure 1



a. Last value recorded before cohabitation.

b. Group III was significantly different from the carrier group (\* $p \leq 0.05$ ).

c. Groups II and III were significantly different from the carrier group (\* $p \leq 0.05$ ).

d. Group II was significantly different from the carrier group (\* $p \leq 0.05$ ).

APPENDIX B  
REPORT TABLES - PART D

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B1 (PAGE 1): CONSUMED DOSAGES (MG/KG/DAY) - PRECOHABITATION - SUMMARY - P GENERATION FEMALE RATS - PART D

DOSAGE GROUP		I	II	III	IV	V
DOSAGE (MG/KG/DAY)		0 (CARRIER)	0.01	0.1	1.0	30.0
RATS TESTED	N	24	24	24	24	24
CONSUMED DOSAGE (MG/KG/DAY)						
DAYS 1 - 7	MEAN±S.D.	0.00 ± 0.00 [ 23]a	0.01 ± 0.00 [ 22]a	0.08 ± 0.02 [ 22]a	0.76 ± 0.12 [ 23]a	23.90 ± 3.05 [ 23]a
DAYS 7 - 15b	MEAN±S.D.	0.00 ± 0.00	0.01 ± 0.00	0.07 ± 0.02	0.64 ± 0.16 [ 23]a	19.92 ± 4.05
DAYS 1 - 15b	MEAN±S.D.	0.00 ± 0.00	0.01 ± 0.00	0.08 ± 0.01	0.70 ± 0.13 [ 23]a	21.69 ± 3.47

DAYS = DAYS OF STUDY

[ ] = NUMBER OF VALUES AVERAGED

a. Excludes values that were associated with spillage or presumed spillage.

b. Last value recorded before cohabitation.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B2 (PAGE 1): CONSUMED DOSAGES (MG/KG/DAY) - GESTATION - SUMMARY - P GENERATION FEMALE RATS - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)		I 0 (CARRIER)	II 0.01	III 0.1	IV 1.0	V 30.0
RATS EVALUATED	N	24	24	24	24	24
PREGNANT	N	19	19	17	20	20
MATERNAL CONSUMED DOSAGE (MG/KG/DAY)						
DAYS 0 - 6	MEAN+S.D.	0.00 ± 0.00	0.01 ± 0.00	0.09 ± 0.02	0.88 ± 0.16 [ 19]a	26.82 ± 4.45
DAYS 6 - 9	MEAN+S.D.	0.00 ± 0.00 [ 17]a	0.01 ± 0.00 [ 17]a	0.09 ± 0.02	0.84 ± 0.21 [ 19]a	26.52 ± 5.46 [ 19]a
DAYS 9 - 12	MEAN+S.D.	0.00 ± 0.00 [ 18]a	0.01 ± 0.00 [ 18]a	0.10 ± 0.02 [ 16]a	0.98 ± 0.24 [ 19]a	28.72 ± 4.17 [ 18]a
DAYS 12 - 15	MEAN+S.D.	0.00 ± 0.00 [ 18]a	0.01 ± 0.00 [ 18]a	0.11 ± 0.02 [ 16]a	0.99 ± 0.20 [ 18]a	29.55 ± 3.84 [ 18]a
DAYS 15 - 18	MEAN+S.D.	0.00 ± 0.00	0.01 ± 0.00 [ 17]a	0.11 ± 0.02 [ 16]a	1.05 ± 0.20	32.51 ± 5.90 [ 18]a
DAYS 18 - 21	MEAN+S.D.	0.00 ± 0.00 [ 18]a	0.01 ± 0.00 [ 17]a	0.08 ± 0.02 [ 16]a	0.86 ± 0.18	26.80 ± 4.67 [ 19]a
DAYS 0 - 21	MEAN+S.D.	0.00 ± 0.00 [ 18]a	0.01 ± 0.00 [ 17]a	0.10 ± 0.02 [ 16]a	0.96 ± 0.20	28.27 ± 3.39 [ 19]a

DAYS = DAYS OF GESTATION

[ ] = NUMBER OF VALUES AVERAGED

a. Excludes values that were associated with spillage or presumed spillage.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B3 (PAGE 1): CLINICAL OBSERVATIONS - SUMMARY - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)	I 0 (CARRIER)	II 0.01	III 0.1	IV 1.0	V 30.0
<u>PRECOHABITATION (DAY 1 OF STUDY TO THE DAY OF COHABITATION):</u>					
MAXIMUM POSSIBLE INCIDENCE	360/ 24	360/ 24	360/ 24	360/ 24	360/ 24
MORTALITY	0	0	0	0	0
RIGHT EAR TORN	0/ 0	0/ 0	0/ 0	0/ 0	15/ 1
<u>PRESUMED GESTATION: a</u>					
MAXIMUM POSSIBLE INCIDENCE b	506/ 23	462/ 21	506/ 23	440/ 20	528/ 24
MORTALITY	0	0	0	0	0
LOCALIZED ALOPECIA: LIMBS	0/ 0	0/ 0	0/ 0	0/ 0	30/ 3**
RIGHT EAR TORN	0/ 0	0/ 0	0/ 0	0/ 0	22/ 1
RED PERIVAGINAL SUBSTANCE	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0

STATISTICAL ANALYSES OF CLINICAL OBSERVATION DATA WERE RESTRICTED TO THE NUMBER OF RATS WITH OBSERVATIONS.

MAXIMUM POSSIBLE INCIDENCE = (DAYS x RATS)/NUMBER OF RATS EXAMINED PER GROUP.

N/N = TOTAL NUMBER OF OBSERVATIONS/NUMBER OF RATS WITH OBSERVATION.

a. Restricted to rats with a confirmed mating date.

b. Includes all rats that were sacrificed on day 21 of presumed gestation.

\*\* Significantly different from the carrier group value ( $p \leq 0.01$ ).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B4 (PAGE 1): NECROPSY OBSERVATIONS - SUMMARY - PART D

DOSAGE GROUP		I	II	III	IV	V
DOSAGE (MG/KG/DAY)		0 (CARRIER)	0.01	0.1	1.0	30.0
RATS EXAMINED a	N	20	20	20	20	20
MORTALITY	N	0	0	0	0	0
APPEARED NORMAL	N	20	20	20	19	20
STOMACH:						
CONTAINED RED SUBSTANCE	N	0	0	0	1	0

a. Refer to the individual clinical observations table (Table B24) for external observations confirmed at necropsy.



PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B5 (PAGE 1): BODY WEIGHTS - PRECOHABITATION - SUMMARY - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)		I 0 (CARRIER)	II 0.01	III 0.1	IV 1.0	V 30.0
RATS TESTED	N	24	24	24	24	24
BODY WEIGHT (G)						
DAY 1	MEAN+S.D	231.8 ± 6.7	231.4 ± 7.3	231.7 ± 5.8	232.3 ± 8.4	233.4 ± 7.5
DAY 2	MEAN+S.D	232.2 ± 7.3	231.3 ± 6.3	232.4 ± 5.5	232.4 ± 8.1	233.9 ± 7.3
DAY 3	MEAN+S.D	235.6 ± 7.1	234.0 ± 8.0	231.0 ± 7.1	234.4 ± 9.7	236.2 ± 9.2
DAY 4	MEAN+S.D	237.8 ± 7.4	236.9 ± 9.3	235.8 ± 7.0	235.6 ± 8.8	238.4 ± 8.0
DAY 5	MEAN+S.D	243.8 ± 7.5	242.4 ± 10.1	242.8 ± 6.3	241.9 ± 10.5	244.4 ± 8.0
DAY 6	MEAN+S.D	244.7 ± 8.4	241.7 ± 10.1	243.3 ± 6.0	243.1 ± 9.6	245.3 ± 9.4
DAY 7	MEAN+S.D	243.5 ± 7.7	240.6 ± 9.8	239.4 ± 6.9	240.9 ± 9.4	243.3 ± 10.6
DAY 8	MEAN+S.D	244.0 ± 9.0	241.3 ± 11.1	240.4 ± 7.1	240.8 ± 11.1	246.2 ± 8.8
DAY 9	MEAN+S.D	243.9 ± 9.3	241.6 ± 10.4	240.7 ± 6.3	241.1 ± 10.2	246.2 ± 9.0
DAY 10	MEAN+S.D	247.8 ± 10.5	244.7 ± 11.4	243.4 ± 7.4	244.3 ± 11.3	250.4 ± 10.8
DAY 11	MEAN+S.D	251.2 ± 10.1	247.5 ± 12.0	244.2 ± 7.6	247.7 ± 10.8	252.0 ± 11.4
DAY 12	MEAN+S.D	255.8 ± 10.6	252.4 ± 12.5	250.8 ± 7.7	251.1 ± 12.4	257.0 ± 11.6
DAY 13	MEAN+S.D	257.1 ± 12.3	255.9 ± 15.3	253.7 ± 8.2	252.4 ± 13.3	259.2 ± 10.9
DAY 14	MEAN+S.D	255.2 ± 12.4	252.9 ± 13.2	252.0 ± 8.4	250.9 ± 11.7	258.4 ± 12.3
DAY 15a	MEAN+S.D	257.6 ± 12.2	254.5 ± 14.8	251.1 ± 10.8	252.5 ± 12.2	259.8 ± 14.0

DAY = DAY OF STUDY

a. Last value recorded before cohabitation.

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TABLE B6 (PAGE 1): BODY WEIGHT CHANGES - PRECOHABITATION - SUMMARY - PART D

DOSAGE GROUP		I	II	III	IV	V
DOSAGE (MG/KG/DAY)		0 (CARRIER)	0.01	0.1	1.0	30.0
RATS TESTED	N	24	24	24	24	24
BODY WEIGHT CHANGE (G)						
DAYS 1 - 7	MEAN±S.D.	+11.7 ± 6.4	+9.2 ± 5.6	+7.7 ± 6.0	+8.6 ± 4.3	+10.0 ± 8.4
DAYS 7 - 15a	MEAN±S.D.	+14.0 ± 6.8	+13.9 ± 7.4	+11.7 ± 6.8	+11.6 ± 5.4	+16.4 ± 6.7
DAYS 1 - 15a	MEAN±S.D.	+25.8 ± 10.7	+23.0 ± 11.0	+19.4 ± 10.5	+20.2 ± 7.0	+26.4 ± 11.9

DAYS = DAYS OF STUDY

a. Last value recorded before cohabitation.

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TABLE B7 (PAGE 1): MATERNAL BODY WEIGHTS AND GRAVID UTERINE WEIGHTS - GESTATION - SUMMARY - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)		I 0 (CARRIER)	II 0.01	III 0.1	IV 1.0	V 30.0
RATS EVALUATED	N	20	20	20	20	20
PREGNANT	N	19	19	17	20	20
MATERNAL BODY WEIGHT (G)						
DAY 0	MEAN±S.D.	261.2 ± 14.3	255.5 ± 13.9	249.2 ± 13.1*	254.8 ± 14.5	263.4 ± 11.3
DAY 1	MEAN±S.D.	271.7 ± 14.1	264.6 ± 13.1	259.9 ± 13.3*	265.3 ± 15.0	275.1 ± 11.8
DAY 2	MEAN±S.D.	277.5 ± 14.0	269.5 ± 13.1	267.9 ± 11.8*	273.2 ± 14.4	281.0 ± 11.0
DAY 3	MEAN±S.D.	280.3 ± 14.8	274.5 ± 14.7	272.8 ± 12.6	276.8 ± 15.1	287.0 ± 11.6
DAY 4	MEAN±S.D.	285.6 ± 15.4	278.3 ± 14.6	276.6 ± 12.5	280.3 ± 15.3	289.9 ± 12.1
DAY 5	MEAN±S.D.	290.8 ± 14.6	280.7 ± 14.8*	280.1 ± 12.4*	284.1 ± 15.1	294.0 ± 11.7
DAY 6	MEAN±S.D.	292.4 ± 14.4	283.9 ± 13.4	284.9 ± 10.8	288.0 ± 15.6	297.1 ± 11.5
DAY 7	MEAN±S.D.	293.8 ± 14.9	287.6 ± 13.7	287.6 ± 10.7	288.2 ± 14.9	299.9 ± 11.8
DAY 8	MEAN±S.D.	297.5 ± 15.2	288.4 ± 13.0	288.7 ± 11.8	291.4 ± 15.7	302.0 ± 12.5
DAY 9	MEAN±S.D.	299.9 ± 13.0	294.0 ± 14.5	294.0 ± 12.0	295.9 ± 16.4	306.6 ± 13.1
DAY 10	MEAN±S.D.	304.6 ± 15.3	297.4 ± 15.0	297.8 ± 12.6	301.0 ± 15.6	311.0 ± 12.2
DAY 11	MEAN±S.D.	314.8 ± 13.2	308.3 ± 16.7	307.9 ± 12.4	309.7 ± 16.3	319.4 ± 12.7

DAY = DAY OF GESTATION

\* Significantly different from the carrier group value ( $p \leq 0.05$ ).

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TABLE B7 (PAGE 2): MATERNAL BODY WEIGHTS AND GRAVID UTERINE WEIGHTS - GESTATION - SUMMARY - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)		I 0 (CARRIER)	II 0.01	III 0.1	IV 1.0	V 30.0
RATS EVALUATED	N	20	20	20	20	20
PREGNANT	N	19	19	17	20	20
MATERNAL BODY WEIGHT (G)						
DAY 12	MEAN+S.D.	322.2 ± 15.2	313.2 ± 17.0	311.8 ± 13.1	316.4 ± 16.8	325.4 ± 12.8
DAY 13	MEAN+S.D.	325.9 ± 14.6	318.5 ± 14.8	319.4 ± 11.9	324.0 ± 17.7	329.9 ± 13.2
DAY 14	MEAN+S.D.	329.9 ± 16.0	321.9 ± 17.1	322.2 ± 13.2	327.6 ± 17.9	336.8 ± 14.1
DAY 15	MEAN+S.D.	338.3 ± 15.5	328.8 ± 17.1	329.5 ± 13.3	333.8 ± 18.4	342.4 ± 13.2
DAY 16	MEAN+S.D.	345.9 ± 16.9	334.9 ± 16.9	337.6 ± 14.7	341.0 ± 20.8	351.2 ± 13.6
DAY 17	MEAN+S.D.	358.1 ± 16.9	347.0 ± 17.2	349.9 ± 15.7	356.0 ± 22.0	363.2 ± 13.7
DAY 18	MEAN+S.D.	375.2 ± 18.6	361.0 ± 18.1*	362.6 ± 20.7	371.1 ± 24.5	377.8 ± 14.8
DAY 19	MEAN+S.D.	391.1 ± 18.9	374.7 ± 20.4*	376.2 ± 24.0	386.5 ± 25.5	392.4 ± 16.6
DAY 20	MEAN+S.D.	405.2 ± 20.4	390.7 ± 20.1	391.8 ± 25.9	405.0 ± 28.7	408.0 ± 18.2
DAY 21	MEAN+S.D.	426.1 ± 22.1	409.7 ± 24.0	411.4 ± 29.0	424.6 ± 30.6	426.2 ± 23.4
GRAVID UTERINE WEIGHTS (G)						
	MEAN+S.D.	103.5 ± 9.2	91.3 ± 20.8	91.2 ± 25.5	105.9 ± 22.6	90.9 ± 23.1
DAY 21C a	MEAN+S.D.	322.6 ± 18.5	318.8 ± 21.8	320.1 ± 12.8	318.8 ± 18.1	335.3 ± 16.3

DAY = DAY OF GESTATION

a. 21C = Corrected maternal body weight (day 21 of gestation body weight minus the gravid uterine weight).

\* Significantly different from the carrier group value (p<0.05).

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TABLE B8 (PAGE 1): MATERNAL BODY WEIGHT CHANGES - GESTATION - SUMMARY - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)		I 0 (CARRIER)	II 0.01	III 0.1	IV 1.0	V 30.0
RATS EVALUATED	N	20	20	20	20	20
PREGNANT	N	19	19	17	20	20
MATERNAL BODY WEIGHT CHANGE (G)						
DAYS 0 - 6	MEAN±S.D.	+31.3 ± 5.6	+28.4 ± 9.0	+35.7 ± 7.3	+33.2 ± 7.7	+33.6 ± 9.2
DAYS 6 - 9	MEAN±S.D.	+7.5 ± 4.1	+10.0 ± 6.9	+9.0 ± 4.0	+8.0 ± 4.9	+9.4 ± 4.0
DAYS 9 - 12	MEAN±S.D.	+22.3 ± 6.1	+19.2 ± 6.3	+17.8 ± 5.6	+20.4 ± 7.1	+18.8 ± 8.2
DAYS 12 - 15	MEAN±S.D.	+16.1 ± 7.6	+15.6 ± 5.7	+17.7 ± 6.4	+17.4 ± 5.0	+17.0 ± 4.0
DAYS 15 - 18	MEAN±S.D.	+36.8 ± 7.6	+32.2 ± 5.4	+33.1 ± 9.2	+37.4 ± 8.9	+35.4 ± 9.5
DAYS 18 - 21	MEAN±S.D.	+50.9 ± 6.7	+48.7 ± 10.2	+48.8 ± 10.9	+53.6 ± 10.1	+48.4 ± 15.3
DAYS 0 - 21	MEAN±S.D.	+164.9 ± 14.4	+154.2 ± 21.4	+162.1 ± 24.1	+169.8 ± 20.6	+162.8 ± 25.2
DAYS 0 - 21C a	MEAN±S.D.	+61.4 ± 11.3	+62.9 ± 11.8	+70.4 ± 14.5*	+64.0 ± 9.3	+71.8 ± 15.6*

DAYS = DAYS OF GESTATION

a. 21C = Corrected maternal body weight (day 21 of gestation body weight minus the gravid uterine weight).

\* Significantly different from the carrier group value ( $p \leq 0.05$ ).

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TABLE B9 (PAGE 1): ABSOLUTE WATER CONSUMPTION VALUES (G/DAY) - PRECOHABITATION - SUMMARY - PART D

DOSAGE GROUP		I	II	III	IV	V
DOSAGE (MG/KG/DAY)		0 (CARRIER)	0.01	0.1	1.0	30.0
RATS TESTED	N	24	24	24	24	24
WATER CONSUMPTION (G/DAY)						
DAYS 1 - 7	MEAN±S.D.	29.0 ± 4.9 [ 23]a	30.8 ± 5.9 [ 22]a	30.9 ± 6.2 [ 22]a	27.4 ± 4.6 [ 23]a	29.0 ± 3.8 [ 23]a
DAYS 7 - 15b	MEAN±S.D.	25.1 ± 5.5	27.6 ± 5.2	26.6 ± 5.9	24.6 ± 6.0 [ 23]a	25.8 ± 5.4
DAYS 1 - 15b	MEAN±S.D.	26.7 ± 4.7	28.8 ± 5.1	28.6 ± 5.4	26.1 ± 5.3 [ 23]a	27.3 ± 4.5

DAYS = DAYS OF STUDY

[ ] = NUMBER OF VALUES AVERAGED

a. Excludes values that were associated with spillage or presumed spillage.

b. Last value recorded before cohabitation.

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TABLE B10 (PAGE 1): RELATIVE WATER CONSUMPTION VALUES (G/KG/DAY) - PRECOHABITATION - SUMMARY - PART D

DOSAGE GROUP		I	II	III	IV	V
DOSAGE (MG/KG/DAY)		0 (CARRIER)	0.01	0.1	1.0	30.0
RATS TESTED	N	24	24	24	24	24
WATER CONSUMPTION (G/KG/DAY)						
DAYS 1 - 7	MEAN±S.D.	121.4 ± 19.7 [ 23]a	130.0 ± 23.9 [ 22]a	130.5 ± 25.2 [ 22]a	115.6 ± 18.0 [ 23]a	121.2 ± 15.4 [ 23]a
DAYS 7 - 15b	MEAN±S.D.	100.1 ± 21.3	111.7 ± 20.6	107.7 ± 22.7	99.7 ± 23.8 [ 23]a	102.4 ± 20.8
DAYS 1 - 15b	MEAN±S.D.	108.6 ± 18.6	118.7 ± 20.4	118.0 ± 21.2	107.5 ± 20.8 [ 23]a	110.6 ± 17.7

DAYS = DAYS OF STUDY

[ ] = NUMBER OF VALUES AVERAGED

a. Excludes values that were associated with spillage or presumed spillage.

b. Last value recorded before cohabitation.

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TABLE B11 (PAGE 1): MATERNAL ABSOLUTE WATER CONSUMPTION VALUES (G/DAY) - GESTATION - SUMMARY - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)		I 0 (CARRIER)	II 0.01	III 0.1	IV 1.0	V 30.0
RATS EVALUATED	N	20	20	20	20	20
PREGNANT	N	19	19	17	20	20
MATERNAL WATER CONSUMPTION (G/DAY)						
DAYS 0 - 6	MEAN±S.D.	32.7 ± 5.6	34.9 ± 6.6	36.0 ± 7.0	34.5 ± 6.3 [ 19]a	34.0 ± 5.8
DAYS 6 - 9	MEAN±S.D.	31.4 ± 6.9 [ 17]a	36.4 ± 7.0 [ 17]a	35.2 ± 6.5	34.0 ± 8.4 [ 19]a	34.2 ± 7.2 [ 19]a
DAYS 9 - 12	MEAN±S.D.	41.7 ± 12.3 [ 18]a	46.2 ± 9.7 [ 18]a	44.2 ± 9.9 [ 16]a	41.9 ± 9.9 [ 19]a	38.9 ± 6.2 [ 18]a
DAYS 12 - 15	MEAN±S.D.	43.8 ± 12.1 [ 18]a	47.7 ± 9.9 [ 18]a	49.8 ± 10.1 [ 16]a	45.0 ± 8.8 [ 18]a	42.4 ± 5.6 [ 18]a
DAYS 15 - 18	MEAN±S.D.	51.0 ± 13.1	52.5 ± 8.7 [ 17]a	55.1 ± 9.5 [ 16]a	52.8 ± 10.4	50.9 ± 9.0 [ 18]a
DAYS 18 - 21	MEAN±S.D.	44.6 ± 9.0 [ 18]a	52.6 ± 11.1 [ 17]a	49.4 ± 9.6 [ 16]a	48.9 ± 10.2	47.6 ± 8.8 [ 19]a
DAYS 0 - 21	MEAN±S.D.	39.7 ± 8.5 [ 18]a	43.0 ± 6.4 [ 17]a	43.7 ± 7.0 [ 16]a	42.6 ± 9.1	39.6 ± 5.0 [ 19]a

DAYS = DAYS OF GESTATION

[ ] = NUMBER OF VALUES AVERAGED

a. Excludes values that were associated with spillage or presumed spillage.



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TABLE B12 (PAGE 1): MATERNAL RELATIVE WATER CONSUMPTION VALUES (G/KG/DAY) - GESTATION - SUMMARY - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)		I 0 (CARRIER)	II 0.01	III 0.1	IV 1.0	V 30.0
RATS EVALUATED	N	20	20	20	20	20
PREGNANT	N	19	19	17	20	20
MATERNAL WATER CONSUMPTION (G/KG/DAY)						
DAYS 0 - 6	MEAN±S.D.	116.7 ± 18.7	128.1 ± 23.8	133.3 ± 26.4	125.8 ± 22.2 [ 19]a	119.6 ± 19.8
DAYS 6 - 9	MEAN±S.D.	106.5 ± 23.7 [ 17]a	126.0 ± 23.0 [ 17]a	121.7 ± 22.0	117.0 ± 28.9 [ 19]a	113.0 ± 23.3 [ 19]a
DAYS 9 - 12	MEAN±S.D.	133.8 ± 38.6 [ 18]a	152.1 ± 28.6 [ 18]a	146.2 ± 33.8 [ 16]a	137.3 ± 33.0 [ 19]a	123.2 ± 17.9 [ 18]a
DAYS 12 - 15	MEAN±S.D.	132.9 ± 36.7 [ 18]a	149.4 ± 29.5 [ 18]a	155.8 ± 33.1* [ 16]a	138.7 ± 27.4 [ 18]a	126.9 ± 16.5 [ 18]a
DAYS 15 - 18	MEAN±S.D.	144.0 ± 37.5	153.5 ± 23.9 [ 17]a	159.9 ± 26.8 [ 16]a	150.6 ± 28.6	142.5 ± 25.9 [ 18]a
DAYS 18 - 21	MEAN±S.D.	111.7 ± 22.4 [ 18]a	137.1 ± 28.8** [ 17]a	128.4 ± 24.2 [ 16]a	123.6 ± 26.3	118.2 ± 20.6 [ 19]a
DAYS 0 - 21	MEAN±S.D.	123.2 ± 26.4 [ 18]a	138.1 ± 19.7 [ 17]a	139.8 ± 22.4 [ 16]a	134.2 ± 28.3	121.5 ± 14.6 [ 19]a

DAYS = DAYS OF GESTATION

[ ] = NUMBER OF VALUES AVERAGED

a. Excludes values that were associated with spillage or presumed spillage.

\* Significantly different from the carrier group value ( $p \leq 0.05$ ).

\*\* Significantly different from the carrier group value ( $p \leq 0.01$ ).

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TABLE B13 (PAGE 1): ABSOLUTE FEED CONSUMPTION VALUES (G/DAY) - PRECOHABITATION - SUMMARY - PART D

DOSAGE GROUP	I	II	III	IV	V
DOSAGE (MG/KG/DAY)	0 (CARRIER)	0.01	0.1	1.0	30.0
RATS TESTED	N	24	24	24	24
FEED CONSUMPTION (G/DAY)					
DAYS 1 - 7	MEAN±S.D.	18.5 ± 1.4	17.8 ± 1.5	17.7 ± 1.4	18.6 ± 1.8
DAYS 7 - 15b	MEAN±S.D.	18.5 ± 2.5 [ 23]a	18.0 ± 2.0	17.5 ± 1.8	18.4 ± 1.5 [ 23]a
DAYS 1 - 15b	MEAN±S.D.	18.5 ± 1.8 [ 23]a	17.9 ± 1.6	17.6 ± 1.5	18.4 ± 1.5

DAYS = DAYS OF STUDY

[ ] = NUMBER OF VALUES AVERAGED

a. Excludes values that were associated with spillage.

b. Last value recorded before cohabitation.

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TABLE B14 (PAGE 1): RELATIVE FEED CONSUMPTION VALUES (G/KG/DAY) - PRECOHABITATION - SUMMARY - PART D

DOSAGE GROUP		I	II	III	IV	V
DOSAGE (MG/KG/DAY)		0 (CARRIER)	0.01	0.1	1.0	30.0
RATS TESTED		N	24	24	24	24
FEED CONSUMPTION (G/KG/DAY)						
DAYS 1 - 7	MEAN±S.D.	77.6 ± 4.6	75.3 ± 5.2	74.9 ± 5.0	74.7 ± 4.4	77.4 ± 6.2 [ 23]a
DAYS 7 - 15b	MEAN±S.D.	73.8 ± 9.2 [ 23]a	72.3 ± 5.8	71.2 ± 6.5	71.0 ± 4.6	72.7 ± 4.4
DAYS 1 - 15b	MEAN±S.D.	75.3 ± 6.0 [ 23]a	73.6 ± 4.7	72.7 ± 5.2	72.5 ± 3.6	74.6 ± 4.6

DAYS = DAYS OF STUDY

[ ] = NUMBER OF VALUES AVERAGED

a. Excludes values that were associated with spillage.

b. Last value recorded before cohabitation.

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TABLE B15 (PAGE 1): MATERNAL ABSOLUTE FEED CONSUMPTION VALUES (G/DAY) - GESTATION - SUMMARY - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)		I 0 (CARRIER)	II 0.01	III 0.1	IV 1.0	V 30.0
RATS EVALUATED	N	20	20	20	20	20
PREGNANT	N	19	19	17	20	20
MATERNAL FEED CONSUMPTION (G/DAY)						
DAYS 0 - 6	MEAN+S.D.	22.9 ± 2.3	21.1 ± 2.0*	21.4 ± 1.4*	22.5 ± 2.6	22.7 ± 2.2
DAYS 6 - 9	MEAN+S.D.	23.7 ± 3.1	22.9 ± 2.5	23.0 ± 2.1	22.4 ± 2.9	23.9 ± 3.4
DAYS 9 - 12	MEAN+S.D.	24.8 ± 1.8	24.0 ± 2.6	23.6 ± 1.8	23.7 ± 2.6	24.8 ± 2.8
DAYS 12 - 15	MEAN+S.D.	23.8 ± 2.9	23.6 ± 2.8	23.9 ± 2.0	24.4 ± 2.0	24.5 ± 2.4
DAYS 15 - 18	MEAN+S.D.	26.6 ± 1.9	25.6 ± 3.0	25.7 ± 2.1	26.4 ± 2.9	27.2 ± 2.4
DAYS 18 - 21	MEAN+S.D.	25.4 ± 2.0	25.2 ± 2.1	24.6 ± 1.9	25.2 ± 2.6	26.0 ± 3.0
DAYS 0 - 21	MEAN+S.D.	24.3 ± 1.6	23.4 ± 1.8	23.3 ± 1.2	23.8 ± 1.7	24.5 ± 1.9

DAYS = DAYS OF GESTATION

\* Significantly different from the carrier group value ( $p \leq 0.05$ ).

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TABLE B16 (PAGE 1): MATERNAL RELATIVE FEED CONSUMPTION VALUES (G/KG/DAY) - GESTATION - SUMMARY - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)		I 0 (CARRIER)	II 0.01	III 0.1	IV 1.0	V 30.0
RATS EVALUATED	N	20	20	20	20	20
PREGNANT	N	19	19	17	20	20
MATERNAL FEED CONSUMPTION (G/KG/DAY)						
DAYS 0 - 6	MEAN±S.D.	81.8 ± 7.5	77.6 ± 5.7	79.1 ± 5.2	81.9 ± 7.7	79.9 ± 6.5
DAYS 6 - 9	MEAN±S.D.	80.0 ± 9.4	79.4 ± 7.1	79.5 ± 6.9	76.8 ± 8.4	79.2 ± 9.7
DAYS 9 - 12	MEAN±S.D.	80.1 ± 5.1	79.0 ± 6.6	77.8 ± 5.1	77.4 ± 7.5	78.5 ± 6.8
DAYS 12 - 15	MEAN±S.D.	72.1 ± 7.8	73.5 ± 5.7	74.6 ± 5.8	74.8 ± 4.5	73.3 ± 6.3
DAYS 15 - 18	MEAN±S.D.	75.0 ± 4.6	74.5 ± 6.2	74.6 ± 4.6	75.2 ± 6.1	75.9 ± 5.4
DAYS 18 - 21	MEAN±S.D.	63.6 ± 4.0	65.6 ± 4.3	63.8 ± 4.1	63.6 ± 5.2	65.0 ± 7.6
DAYS 0 - 21	MEAN±S.D.	75.4 ± 3.8	74.6 ± 3.1	74.7 ± 3.2	75.0 ± 3.0	75.2 ± 4.3
DAYS = DAYS OF GESTATION						

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TABLE B17 (PAGE 1): CAESAREAN-SECTIONING OBSERVATIONS - SUMMARY - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)		I 0 (CARRIER)		II 0.01		III 0.1		IV 1.0		V 30.0	
RATS EVALUATED		N	20	20	20	20	20	20	20		
PREGNANT		N(%)	19( 95.0)	19( 95.0)	17( 85.0)	20(100.0)	20(100.0)				
RATS PREGNANT AND CAESAREAN-SECTIONED ON DAY 21 OF GESTATION		N	19	19	17	20	20				
CORPORA LUTEA	MEAN+S.D.	19.3 ± 2.8	17.9 ± 2.3	18.1 ± 2.6	19.8 ± 3.1	19.8 ± 4.2					
IMPLANTATIONS	MEAN+S.D.	17.0 ± 1.6	14.7 ± 3.7	14.4 ± 4.3	16.6 ± 3.6	14.8 ± 3.9					
LITTER SIZES	MEAN+S.D.	16.6 ± 1.5	14.3 ± 3.7	13.9 ± 4.3	16.2 ± 3.6	14.1 ± 3.8*					
LIVE FETUSES	N	316	271	236	325	282					
	MEAN+S.D.	16.6 ± 1.5	14.3 ± 3.7	13.9 ± 4.3	16.2 ± 3.6	14.1 ± 3.8*					
DEAD FETUSES	N	0	0	0	0	0					
RESORPTIONS	MEAN+S.D.	0.4 ± 0.6	0.5 ± 0.8	0.5 ± 0.7	0.4 ± 0.7	0.8 ± 1.0					
EARLY RESORPTIONS	N	7	8	8	8	15					
	MEAN+S.D.	0.4 ± 0.6	0.4 ± 0.8	0.5 ± 0.7	0.4 ± 0.7	0.8 ± 1.0					
LATE RESORPTIONS	N	0	1	0	0	0					
	MEAN+S.D.	0.0 ± 0.0	0.0 ± 0.2	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0					
DAMS WITH ANY RESORPTIONS	N(%)	6( 31.6)	6( 31.6)	6( 35.3)	6( 30.0)	10( 50.0)					
DAMS WITH ALL CONCEPTUSES RESORBED	N(%)	0( 0.0)	0( 0.0)	0( 0.0)	0( 0.0)	0( 0.0)					
DAMS WITH VIABLE FETUSES	N(%)	19(100.0)	19(100.0)	17(100.0)	20(100.0)	20(100.0)					
PLACENTAE APPEARED NORMAL	N(%)	19(100.0)	19(100.0)	17(100.0)	20(100.0)	20(100.0)					

\* Significantly different from the carrier group value ( $p \leq 0.05$ ).

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TABLE B18 (PAGE 1): LITTER OBSERVATIONS (CAESAREAN-DELIVERED FETUSES) - SUMMARY - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)		I 0 (CARRIER)	II 0.01	III 0.1	IV 1.0	V 30.0
LITTERS WITH ONE OR MORE LIVE FETUSES		N	19	19	17	20
IMPLANTATIONS	MEAN±S.D.	17.0 ± 1.6	14.7 ± 3.7	14.4 ± 4.3	16.6 ± 3.6	14.8 ± 3.9
LIVE FETUSES	N	316	271	236	325	282
	MEAN±S.D.	16.6 ± 1.5	14.3 ± 3.7	13.9 ± 4.3	16.2 ± 3.6	14.1 ± 3.8*
LIVE MALE FETUSES	N	149	140	118	162	141
% LIVE MALE FETUSES/LITTER	MEAN±S.D.	47.2 ± 9.9	53.0 ± 17.0	47.3 ± 19.0	50.9 ± 13.4	47.8 ± 17.4
LIVE FETAL BODY WEIGHTS (GRAMS)/LITTER	MEAN±S.D.	4.30 ± 0.20	4.45 ± 0.37	4.62 ± 0.53	4.54 ± 0.31	4.49 ± 0.67
MALE FETUSES	MEAN±S.D.	4.40 ± 0.20	4.59 ± 0.39	4.74 ± 0.51* [ 16]a	4.68 ± 0.30*	4.48 ± 0.39 [ 19]b
FEMALE FETUSES	MEAN±S.D.	4.20 ± 0.19	4.28 ± 0.35	4.49 ± 0.56	4.40 ± 0.29	4.38 ± 0.69
% RESORBED CONCEPTUSES/LITTER	MEAN±S.D.	2.1 ± 3.4	3.1 ± 5.5	4.1 ± 7.1	2.3 ± 4.0	6.7 ± 11.7

[ ] = NUMBER OF VALUES AVERAGED

a. Litter 19172 had no male fetuses.

b. Litter 19215 had no male fetuses.

\* Significantly different from the carrier group value ( $p \leq 0.05$ ).

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TABLE B19 (PAGE 1): FETAL ALTERATIONS - SUMMARY - PART D

DOSAGE GROUP		I	II	III	IV	V
DOSAGE (MG/KG/DAY)		0 (CARRIER)	0.01	0.1	1.0	30.0
LITTERS EVALUATED	N	19	19	17	20	20
FETUSES EVALUATED	N	316	271	236	325	282
LIVE	N	316	271	236	325	282
LITTERS WITH FETUSES WITH ANY ALTERATION OBSERVED	N(%)	7( 36.8)	4( 21.0)	8( 47.0)	4( 20.0)	4( 20.0)
FETUSES WITH ANY ALTERATION OBSERVED	N(%)	8( 2.5)	4( 1.5)	12( 5.1)**	5( 1.5)	5( 1.8)
% FETUSES WITH ANY ALTERATION/LITTER	MEAN±S.D.	2.6 ± 3.8	1.3 ± 2.6	5.2 ± 6.3	1.5 ± 3.1	1.9 ± 3.9

\*\* Significantly different from the carrier group value ( $p \leq 0.01$ ).



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TABLE B20 (PAGE 1): FETAL GROSS EXTERNAL ALTERATIONS - SUMMARY - PART D

DOSAGE GROUP		I	II	III	IV	V
DOSAGE (MG/KG/DAY)		0 (CARRIER)	0.01	0.1	1.0	30.0
LITTERS EVALUATED	N	19	19	17	20	20
FETUSES EVALUATED	N	316	271	236	325	282
LIVE	N	316	271	236	325	282
SNOUT: CLEFT						
LITTER INCIDENCE	N(%)	0( 0.0)	1( 5.3)	0( 0.0)	0( 0.0)	0( 0.0)
FETAL INCIDENCE	N(%)	0( 0.0)	1( 0.4)a	0( 0.0)	0( 0.0)	0( 0.0)
PALATE: CLEFT						
LITTER INCIDENCE	N(%)	0( 0.0)	1( 5.3)	0( 0.0)	0( 0.0)	0( 0.0)
FETAL INCIDENCE	N(%)	0( 0.0)	1( 0.4)a	0( 0.0)	0( 0.0)	0( 0.0)

a. Fetus 19144-9 had other gross external alterations.

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TABLE B21 (PAGE 1): FETAL SOFT TISSUE ALTERATIONS - SUMMARY - PART D

DOSAGE GROUP		I	II	III	IV	V
DOSAGE (MG/KG/DAY)		0 (CARRIER)	0.01	0.1	1.0	30.0
LITTERS EVALUATED	N	19	19	17	20	19
FETUSES EVALUATED	N	153	131	112	158	137
LIVE	N	153	131	112	158	137
VESSELS: INNOMINATE ABSENT						
LITTER INCIDENCE	N(%)	2( 10.5)	0( 0.0)	3( 17.6)	1( 5.0)	0( 0.0)
FETAL INCIDENCE	N(%)	2( 1.3)a	0( 0.0)	3( 2.7)	1( 0.6)	0( 0.0)
VESSELS: UMBILICAL ARTERY DESCENDED TO THE LEFT OF THE URINARY BLADDER						
LITTER INCIDENCE	N(%)	1( 5.3)	0( 0.0)	0( 0.0)	0( 0.0)	0( 0.0)
FETAL INCIDENCE	N(%)	1( 0.6)	0( 0.0)	0( 0.0)	0( 0.0)	0( 0.0)
VESSELS: AORTIC ARCH BIFURCATED						
LITTER INCIDENCE	N(%)	1( 5.3)	0( 0.0)	0( 0.0)	0( 0.0)	0( 0.0)
FETAL INCIDENCE	N(%)	1( 0.6)a	0( 0.0)	0( 0.0)	0( 0.0)	0( 0.0)
URETER: DISTENDED						
LITTER INCIDENCE	N(%)	0( 0.0)	1( 5.3)	0( 0.0)	0( 0.0)	0( 0.0)
FETAL INCIDENCE	N(%)	0( 0.0)	1( 0.8)	0( 0.0)	0( 0.0)	0( 0.0)

a. Fetus 19114-12 had other soft tissue alterations.

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TABLE B22 (PAGE 1): FETAL SKELETAL ALTERATIONS - SUMMARY - PART D  
(See footnotes on the last page of this table.)

DOSAGE GROUP		I	II	III	IV	V
DOSAGE (MG/KG/DAY)		0 (CARRIER)	0.01	0.1	1.0	30.0
LITTERS EVALUATED	N	19	19	17	20	20
FETUSES EVALUATED	N	163	140	124	167	145
LIVE	N	163	140	124	167	145
SKULL: MAXILLAE, INCOMPLETELY OSSIFIED						
LITTER INCIDENCE	N(%)	0( 0.0)	1( 5.3)	0( 0.0)	0( 0.0)	0( 0.0)
FETAL INCIDENCE	N(%)	0( 0.0)	1( 0.7)b	0( 0.0)	0( 0.0)	0( 0.0)
SKULL: PALATE, INCOMPLETELY OSSIFIED						
LITTER INCIDENCE	N(%)	0( 0.0)	1( 5.3)	0( 0.0)	0( 0.0)	0( 0.0)
FETAL INCIDENCE	N(%)	0( 0.0)	1( 0.7)b	0( 0.0)	0( 0.0)	0( 0.0)
CERVICAL VERTEBRAE: CERVICAL RIB PRESENT AT 7TH CERVICAL VERTEBRA						
LITTER INCIDENCE	N(%)	4( 21.0)	2( 10.5)	4( 23.5)	1( 5.0)	1( 5.0)
FETAL INCIDENCE	N(%)	4( 2.4)	2( 1.4)	5( 4.0)	1( 0.6)	1( 0.7)
THORACIC VERTEBRAE: CENTRUM, BIFID						
LITTER INCIDENCE	N(%)	0( 0.0)	1( 5.3)	1( 5.9)	2( 10.0)	0( 0.0)
FETAL INCIDENCE	N(%)	0( 0.0)	1( 0.7)b	2( 1.6)	3( 1.8)	0( 0.0)
RIBS: WAVY						
LITTER INCIDENCE	N(%)	0( 0.0)	0( 0.0)	0( 0.0)	0( 0.0)	1( 5.0)
FETAL INCIDENCE	N(%)	0( 0.0)	0( 0.0)	0( 0.0)	0( 0.0)	2( 1.4)e
RIBS: INCOMPLETELY OSSIFIED (HYPOPLASTIC)						
LITTER INCIDENCE	N(%)	0( 0.0)	0( 0.0)	0( 0.0)	0( 0.0)	1( 5.0)
FETAL INCIDENCE	N(%)	0( 0.0)	0( 0.0)	0( 0.0)	0( 0.0)	1( 0.7)e

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TABLE B22 (PAGE 2): FETAL SKELETAL ALTERATIONS - SUMMARY - PART D  
(See footnotes on the last page of this table.)

DOSAGE GROUP		I	II	III	IV	V
DOSAGE (MG/KG/DAY)		0 (CARRIER)	0.01	0.1	1.0	30.0
LITTERS EVALUATED	N	19	19	17	20	20
FETUSES EVALUATED	N	163	140	124	167	145
LIVE	N	163	140	124	167	145
STERNAL CENTRA: SUMMARIZATION (Includes incompletely ossified asymmetric and fused sternal centra):						
LITTER INCIDENCE	N(%)	1( 5.3)	1( 5.3)	1( 5.9)	0( 0.0)	1( 5.0)
FETAL INCIDENCE	N(%)	1( 0.6)	1( 0.7)	1( 0.8)	0( 0.0)	1( 0.7)
STERNAL CENTRA: INCOMPLETELY OSSIFIED						
LITTER INCIDENCE	N(%)	0( 0.0)	1( 5.3)	1( 5.9)	0( 0.0)	1( 5.0)
FETAL INCIDENCE	N(%)	0( 0.0)	1( 0.7)b	1( 0.8)c	0( 0.0)	1( 0.7)
STERNAL CENTRA: ASYMMETRIC						
LITTER INCIDENCE	N(%)	1( 5.3)	0( 0.0)	0( 0.0)	0( 0.0)	0( 0.0)
FETAL INCIDENCE	N(%)	1( 0.6)a	0( 0.0)	0( 0.0)	0( 0.0)	0( 0.0)
STERNAL CENTRA: FUSED						
LITTER INCIDENCE	N(%)	1( 5.3)	0( 0.0)	0( 0.0)	0( 0.0)	0( 0.0)
FETAL INCIDENCE	N(%)	1( 0.6)a	0( 0.0)	0( 0.0)	0( 0.0)	0( 0.0)

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B22 (PAGE 3): FETAL SKELETAL ALTERATIONS - SUMMARY - PART D

DOSAGE GROUP		I	II	III	IV	V
DOSAGE (MG/KG/DAY)		0 (CARRIER)	0.01	0.1	1.0	30.0
LITTERS EVALUATED	N	19	19	17	20	20
FETUSES EVALUATED	N	163	140	124	167	145
LIVE	N	163	140	124	167	145
PELVIS: SUMMARIZATION (Includes not ossified pubes and incompletely ossified pubes and ischia):						
LITTER INCIDENCE	N(%)	0( 0.0)	0( 0.0)	2( 11.8)	0( 0.0)	1( 5.0)
FETAL INCIDENCE	N(%)	0( 0.0)	0( 0.0)	2( 1.6)	0( 0.0)	1( 0.7)
PELVIS: PUBIS, NOT OSSIFIED						
LITTER INCIDENCE	N(%)	0( 0.0)	0( 0.0)	1( 5.9)	0( 0.0)	1( 5.0)
FETAL INCIDENCE	N(%)	0( 0.0)	0( 0.0)	1( 0.8)c	0( 0.0)	1( 0.7)
PELVIS: ISCHIUM, INCOMPLETELY OSSIFIED						
LITTER INCIDENCE	N(%)	0( 0.0)	0( 0.0)	1( 5.9)	0( 0.0)	0( 0.0)
FETAL INCIDENCE	N(%)	0( 0.0)	0( 0.0)	1( 0.8)d	0( 0.0)	0( 0.0)
PELVIS: PUBIS, INCOMPLETELY OSSIFIED						
LITTER INCIDENCE	N(%)	0( 0.0)	0( 0.0)	1( 5.9)	0( 0.0)	0( 0.0)
FETAL INCIDENCE	N(%)	0( 0.0)	0( 0.0)	1( 0.8)d	0( 0.0)	0( 0.0)

- a. Fetus 19113-3 had other skeletal alterations.
- b. Fetus 19144-9 had other skeletal alterations.
- c. Fetus 19150-1 had other skeletal alterations.
- d. Fetus 19164-7 had other skeletal alterations.
- e. Fetus 19208-5 had other skeletal alterations.

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TABLE B23 (PAGE 1): FETAL OSSIFICATION SITES - CAESAREAN-DELIVERED LIVE FETUSES (DAY 21 OF GESTATION) - SUMMARY - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)		I 0 (CARRIER)	II 0.01	III 0.1	IV 1.0	V 30.0
LITTERS EXAMINED	N	19	19	17	20	20
FETUSES EXAMINED	N	163	140	124	167	145
OSSIFICATION SITES PER FETUS PER LITTER						
HYOID	MEAN+S.D.	0.98 ± 0.05	0.99 ± 0.03	0.98 ± 0.06	0.97 ± 0.07	1.00 ± 0.00
VERTEBRAE						
CERVICAL	MEAN+S.D.	7.00 ± 0.00	7.00 ± 0.00	7.00 ± 0.00	7.00 ± 0.00	7.00 ± 0.00
THORACIC	MEAN+S.D.	13.10 ± 0.17	13.19 ± 0.29	13.07 ± 0.15	13.12 ± 0.16	13.02 ± 0.07
LUMBAR	MEAN+S.D.	5.90 ± 0.17	5.80 ± 0.29	5.93 ± 0.15	5.88 ± 0.16	5.97 ± 0.08
SACRAL	MEAN+S.D.	3.00 ± 0.00	3.00 ± 0.00	3.00 ± 0.00	3.00 ± 0.00	3.00 ± 0.00
CAUDAL	MEAN+S.D.	6.47 ± 0.49	6.69 ± 0.68	6.50 ± 1.00	6.44 ± 0.64	6.19 ± 1.54
RIBS (PAIRS)	MEAN+S.D.	13.06 ± 0.13	13.13 ± 0.18	13.05 ± 0.11	13.08 ± 0.14	13.01 ± 0.03
STERNUM						
MANUBRIUM	MEAN+S.D.	1.00 ± 0.00	1.00 ± 0.00	1.00 ± 0.00	1.00 ± 0.00	1.00 ± 0.00
STERNAL CENTERS	MEAN+S.D.	4.00 ± 0.00	3.93 ± 0.14	3.97 ± 0.08	3.96 ± 0.08	3.88 ± 0.15**
XIPHOID	MEAN+S.D.	1.00 ± 0.00	1.00 ± 0.00	0.99 ± 0.02	1.00 ± 0.02	1.00 ± 0.00
FORELIMB a						
CARPALS	MEAN+S.D.	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
METACARPALS	MEAN+S.D.	4.00 ± 0.00	3.99 ± 0.03	3.99 ± 0.02	3.99 ± 0.03	3.94 ± 0.14
DIGITS	MEAN+S.D.	5.00 ± 0.00	5.00 ± 0.00	5.00 ± 0.00	5.00 ± 0.00	5.00 ± 0.00
PHALANGES	MEAN+S.D.	6.97 ± 0.44	6.78 ± 0.50	6.68 ± 0.69	7.01 ± 0.60	6.43 ± 0.90*
HINDLIMB a						
TARSALS	MEAN+S.D.	0.00 ± 0.00	0.00 ± 0.00	0.02 ± 0.10	0.00 ± 0.00	0.05 ± 0.22
METATARSALS	MEAN+S.D.	4.20 ± 0.26	4.17 ± 0.24	4.14 ± 0.29	4.09 ± 0.15	4.14 ± 0.30
DIGITS	MEAN+S.D.	5.00 ± 0.00	5.00 ± 0.00	5.00 ± 0.00	5.00 ± 0.00	5.00 ± 0.00
PHALANGES	MEAN+S.D.	5.03 ± 0.11	5.03 ± 0.08	5.19 ± 0.94	5.01 ± 0.04	5.22 ± 0.89

a. Calculated as average per limb.

\* Significantly different from the carrier group value ( $p \leq 0.05$ ).

\*\* Significantly different from the carrier group value ( $p \leq 0.01$ ).

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TABLE B24 (PAGE 1): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP I		0 (CARRIER) MG/KG/DAY
RAT #	DESCRIPTION	
19101	NO ADVERSE FINDINGS	
19102	NO ADVERSE FINDINGS	
19103	NO ADVERSE FINDINGS	
19104	NO ADVERSE FINDINGS	
19105	NO ADVERSE FINDINGS	
19106	NO ADVERSE FINDINGS	
19107	NO ADVERSE FINDINGS	
19108	NO ADVERSE FINDINGS	
19109	NO ADVERSE FINDINGS	
19110	NO ADVERSE FINDINGS	
19111	NO ADVERSE FINDINGS	
19112	NO ADVERSE FINDINGS	
19113	NO ADVERSE FINDINGS	
19114	NO ADVERSE FINDINGS	
19115	NO ADVERSE FINDINGS	
19116	NO ADVERSE FINDINGS	
19117	NO ADVERSE FINDINGS	
19118	NO ADVERSE FINDINGS	
19119	NO ADVERSE FINDINGS	
19120	NO ADVERSE FINDINGS	
19121	NO ADVERSE FINDINGS	
19122	NO ADVERSE FINDINGS	
19123	NO ADVERSE FINDINGS	
19124	NO ADVERSE FINDINGS	
DS = DAY OF STUDY		DG = DAY OF PRESUMED GESTATION

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B24 (PAGE 2): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP II		0.01 MG/KG/DAY
RAT #	DESCRIPTION	
19125	NO ADVERSE FINDINGS	
19126	NO ADVERSE FINDINGS	
19127	NO ADVERSE FINDINGS	
19128	NO ADVERSE FINDINGS	
19129	NO ADVERSE FINDINGS	
19130	NO ADVERSE FINDINGS	
19131	NO ADVERSE FINDINGS	
19132	NO ADVERSE FINDINGS	
19133	NO ADVERSE FINDINGS	
19134	NO ADVERSE FINDINGS	
19135	NO ADVERSE FINDINGS	
19136	NO ADVERSE FINDINGS	
19137	NO ADVERSE FINDINGS	
19138	NO ADVERSE FINDINGS	
19139	NO ADVERSE FINDINGS	
19140	NO ADVERSE FINDINGS	
19141	NO ADVERSE FINDINGS	
19142	NO ADVERSE FINDINGS	
19143	NO ADVERSE FINDINGS	
19144	NO ADVERSE FINDINGS	
19145	NO ADVERSE FINDINGS	
19146	NO ADVERSE FINDINGS	
19147	NO ADVERSE FINDINGS	
19148	NO ADVERSE FINDINGS	

DS = DAY OF STUDY

DG = DAY OF PRESUMED GESTATION



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TABLE B24 (PAGE 3): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP III		0.1 MG/KG/DAY
RAT #	DESCRIPTION	
19149	NO ADVERSE FINDINGS	
19150	NO ADVERSE FINDINGS	
19151	NO ADVERSE FINDINGS	
19152	NO ADVERSE FINDINGS	
19153	NO ADVERSE FINDINGS	
19154	NO ADVERSE FINDINGS	
19155	NO ADVERSE FINDINGS	
19156	NO ADVERSE FINDINGS	
19157	NO ADVERSE FINDINGS	
19158	NO ADVERSE FINDINGS	
19159	NO ADVERSE FINDINGS	
19160	NO ADVERSE FINDINGS	
19161	NO ADVERSE FINDINGS	
19162	NO ADVERSE FINDINGS	
19163	NO ADVERSE FINDINGS	
19164	NO ADVERSE FINDINGS	
19165	NO ADVERSE FINDINGS	
19166	NO ADVERSE FINDINGS	
19167	NO ADVERSE FINDINGS	
19168	NO ADVERSE FINDINGS	
19169	NO ADVERSE FINDINGS	
19170	NO ADVERSE FINDINGS	
19171	NO ADVERSE FINDINGS	
19172	NO ADVERSE FINDINGS	

DS = DAY OF STUDY

DG = DAY OF PRESUMED GESTATION

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B24 (PAGE 4): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP IV		1.0 MG/KG/DAY
RAT #		DESCRIPTION
19173		NO ADVERSE FINDINGS
19174		NO ADVERSE FINDINGS
19175		NO ADVERSE FINDINGS
19176		NO ADVERSE FINDINGS
19177		NO ADVERSE FINDINGS
19178		NO ADVERSE FINDINGS
19179		NO ADVERSE FINDINGS
19180		NO ADVERSE FINDINGS
19181		NO ADVERSE FINDINGS
19182		NO ADVERSE FINDINGS
19183		NO ADVERSE FINDINGS
19184		NO ADVERSE FINDINGS
19185		NO ADVERSE FINDINGS
19186		NO ADVERSE FINDINGS
19187		NO ADVERSE FINDINGS
19188		NO ADVERSE FINDINGS
19189	DG( 21 )	RED PERIVAGINAL SUBSTANCE a
19190		NO ADVERSE FINDINGS
19191		NO ADVERSE FINDINGS
19192		NO ADVERSE FINDINGS
19193		NO ADVERSE FINDINGS
19194		NO ADVERSE FINDINGS
19195		NO ADVERSE FINDINGS
19196		NO ADVERSE FINDINGS

DS = DAY OF STUDY                      DG = DAY OF PRESUMED GESTATION

a. Observation confirmed at necropsy.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B24 (PAGE 5): CLINICAL OBSERVATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP V		30.0 MG/KG/DAY
RAT #		DESCRIPTION
19197		NO ADVERSE FINDINGS
19198		NO ADVERSE FINDINGS
19199	DG( 11- 21)	LOCALIZED ALOPECIA: LIMBS a
19200		NO ADVERSE FINDINGS
19201		NO ADVERSE FINDINGS
19202		NO ADVERSE FINDINGS
19203		NO ADVERSE FINDINGS
19204		NO ADVERSE FINDINGS
19205		NO ADVERSE FINDINGS
19206		NO ADVERSE FINDINGS
19207		NO ADVERSE FINDINGS
19208		NO ADVERSE FINDINGS
19209	DG( 13- 21)	LOCALIZED ALOPECIA: LIMBS
19210		NO ADVERSE FINDINGS
19211		NO ADVERSE FINDINGS
19212		NO ADVERSE FINDINGS
19213		NO ADVERSE FINDINGS
19214		NO ADVERSE FINDINGS
19215	DG( 12- 21)	LOCALIZED ALOPECIA: LIMBS a
19216		NO ADVERSE FINDINGS
19217		NO ADVERSE FINDINGS
19218		NO ADVERSE FINDINGS
19219		NO ADVERSE FINDINGS
19220	DS( 1- 16)	RIGHT EAR TORN
	DG( 0- 21)	RIGHT EAR TORN a

DS = DAY OF STUDY      DG = DAY OF PRESUMED GESTATION

a. Observation confirmed at necropsy.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B25 (PAGE 1): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)	RAT NUMBER	DAY OF NECROPSY	PREGNANCY STATUS	DAYS OF EXPOSURE	OBSERVATIONS a
I					
0 (CARRIER)	19101	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19102	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19103	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19104	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19105	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19107	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19108	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19109	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19110	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19111	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19112	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19113	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19114	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19115	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19116	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19117	DG 21	P	39	ALL TISSUES APPEARED NORMAL.
	19119	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19120	DG 21	NP	37	ALL TISSUES APPEARED NORMAL.
	19123	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19124	DG 21	P	36	ALL TISSUES APPEARED NORMAL.

DG = DAY OF PRESUMED GESTATION

P = PREGNANT NP = NOT PREGNANT

a. Refer to the individual clinical observations table (Table B24) for external observations confirmed at necropsy.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B25 (PAGE 2): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)	RAT NUMBER	DAY OF NECROPSY	PREGNANCY STATUS	DAYS OF EXPOSURE	OBSERVATIONS a
II					
0.01	19125	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19127	DG 21	NP	38	ALL TISSUES APPEARED NORMAL.
	19128	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19130	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19131	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19132	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19133	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19134	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19135	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19136	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19137	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19139	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19140	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19141	DG 21	P	44	ALL TISSUES APPEARED NORMAL.
	19143	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19144	DG 21	P	39	ALL TISSUES APPEARED NORMAL.
	19145	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19146	DG 21	P	40	ALL TISSUES APPEARED NORMAL.
	19147	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19148	DG 21	P	38	ALL TISSUES APPEARED NORMAL.

DG = DAY OF PRESUMED GESTATION

P = PREGNANT NP = NOT PREGNANT

a. Refer to the individual clinical observations table (Table B24) for external observations confirmed at necropsy.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B25 (PAGE 3): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)	RAT NUMBER	DAY OF NECROPSY	PREGNANCY STATUS	DAYS OF EXPOSURE	OBSERVATIONS a
III					
0.1	19150	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19151	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19152	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19153	DG 21	NP	36	ALL TISSUES APPEARED NORMAL.
	19155	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19156	DG 21	NP	37	ALL TISSUES APPEARED NORMAL.
	19157	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19158	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19159	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19160	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19161	DG 21	P	39	ALL TISSUES APPEARED NORMAL.
	19162	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19164	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19165	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19166	DG 21	NP	36	ALL TISSUES APPEARED NORMAL.
	19167	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19168	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19170	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19171	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19172	DG 21	P	36	ALL TISSUES APPEARED NORMAL.

DG = DAY OF PRESUMED GESTATION

P = PREGNANT NP = NOT PREGNANT

a. Refer to the individual clinical observations table (Table B24) for external observations confirmed at necropsy.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B25 (PAGE 4): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)	RAT NUMBER	DAY OF NECROPSY	PREGNANCY STATUS	DAYS OF EXPOSURE	OBSERVATIONS a
IV 1.0	19173	DG 21	P	39	ALL TISSUES APPEARED NORMAL.
	19174	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19175	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19176	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19177	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19178	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19179	DG 21	P	39	ALL TISSUES APPEARED NORMAL.
	19180	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19181	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19182	DG 21	P	39	ALL TISSUES APPEARED NORMAL.
	19184	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19185	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19186	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19187	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19188	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19189	DG 21	P	36	STOMACH: CONTAINED RED SUBSTANCE. ALL OTHER TISSUES APPEARED NORMAL.
	19190	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19191	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19193	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19196	DG 21	P	38	ALL TISSUES APPEARED NORMAL.

DG = DAY OF PRESUMED GESTATION

P = PREGNANT NP = NOT PREGNANT

a. Refer to the individual clinical observations table (Table B24) for external observations confirmed at necropsy.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B25 (PAGE 5): NECROPSY OBSERVATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP DOSAGE (MG/KG/DAY)	RAT NUMBER	DAY OF NECROPSY	PREGNANCY STATUS	DAYS OF EXPOSURE	OBSERVATIONS a
V 30.0	19197	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19198	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19199	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19200	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19201	DG 21	P	39	ALL TISSUES APPEARED NORMAL.
	19202	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19204	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19205	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19206	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19207	DG 21	P	38	ALL TISSUES APPEARED NORMAL.
	19208	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19210	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19211	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19212	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19213	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19215	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19216	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19218	DG 21	P	36	ALL TISSUES APPEARED NORMAL.
	19219	DG 21	P	37	ALL TISSUES APPEARED NORMAL.
	19220	DG 21	P	37	ALL TISSUES APPEARED NORMAL.

DG = DAY OF PRESUMED GESTATION

P = PREGNANT NP = NOT PREGNANT

a. Refer to the individual clinical observations table (Table B24) for external observations confirmed at necropsy.



PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B26 (PAGE 1): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15a	16
RAT #	DOSAGE GROUP I					0 (CARRIER) MG/KG/DAY										
19101	228.	226.	238.	236.	242.	235.	243.	246.	244.	243.	251.	255.	251.	248.	251.	258.
19102	240.	248.	253.	252.	251.	257.	243.	253.	254.	264.	268.	272.	272.	267.	277.	272.
19103	234.	231.	228.	238.	245.	238.	242.	248.	246.	248.	248.	253.	255.	246.	255.	265.
19104	214.	223.	230.	228.	228.	238.	236.	229.	228.	238.	239.	246.	242.	246.	249.	250.
19105	229.	226.	230.	234.	242.	241.	240.	240.	242.	242.	247.	255.	260.	252.	257.	256.
19106	237.	242.	244.	250.	257.	253.	255.	255.	252.	256.	259.	267.	267.	262.	264.	266.
19107	240.	230.	236.	238.	244.	239.	237.	242.	242.	240.	250.	251.	250.	239.	239.	249.
19108	220.	217.	217.	221.	226.	222.	223.	220.	221.	221.	225.	226.	225.	221.	226.	232.
19109	225.	220.	228.	231.	237.	233.	232.	234.	234.	233.	237.	247.	239.	238.	240.	247.
19110	230.	233.	241.	239.	241.	242.	244.	243.	231.	250.	256.	255.	249.	253.	259.	260.
19111	235.	240.	242.	235.	243.	254.	252.	249.	254.	266.	266.	268.	267.	272.	273.	266.
19112	234.	233.	234.	240.	247.	244.	242.	247.	248.	257.	251.	249.	254.	257.	255.	258.
19113	225.	228.	232.	237.	241.	245.	243.	241.	240.	246.	252.	259.	261.	268.	267.	264.
19114	239.	237.	241.	247.	251.	252.	251.	253.	250.	250.	255.	263.	265.	261.	264.	270.
19115	239.	234.	241.	249.	252.	251.	254.	258.	257.	259.	268.	272.	275.	269.	274.	280.
19116	223.	227.	230.	232.	233.	241.	236.	234.	231.	235.	240.	240.	240.	246.	246.	238.
19117	234.	228.	236.	243.	250.	248.	244.	253.	252.	256.	256.	265.	271.	267.	257.	263.
19118	237.	238.	236.	240.	245.	246.	240.	241.	244.	248.	243.	254.	260.	258.	250.	257.
19119	235.	233.	235.	236.	243.	240.	242.	242.	241.	243.	248.	255.	256.	249.	255.	263.
19120	232.	233.	235.	228.	238.	243.	242.	236.	242.	244.	245.	246.	258.	255.	256.	255.
19121	234.	240.	232.	240.	251.	254.	250.	252.	254.	260.	258.	264.	250.	251.	270.	267.
19122	234.	239.	242.	245.	248.	253.	255.	252.	249.	241.	258.	264.	268.	265.	269.	269.
19123	228.	230.	234.	233.	248.	251.	249.	247.	248.	253.	254.	254.	267.	267.	268.	
19124	238.	238.	240.	236.	248.	253.	250.	241.	250.	253.	256.	258.	268.	268.	261.	

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Last value recorded before cohabitation.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B26 (PAGE 2): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAY	17	18	19
RAT #	DOSAGE GROUP I	0 (CARRIER)	MG/KG/DAY
19101	260.		
19102			
19103	263.		
19104			
19105	260.		
19106	271.	267.	276.
19107			
19108	233.		
19109	248.		
19110			
19111			
19112			
19113			
19114	272.		
19115	278.		
19116			
19117	270.	272.	
19118	260.	256.	
19119	268.		
19120			
19121	274.	278.	
19122	276.	272.	273.
19123			
19124			

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B26 (PAGE 3): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15a	16
RAT #	DOSAGE GROUP II 0.01 MG/KG/DAY															
19125	223.	222.	224.	226.	228.	230.	227.	230.	229.	232.	236.	241.	245.	242.	246.	254.
19126	240.	238.	235.	244.	249.	251.	243.	242.	245.	246.	246.	252.	260.	261.	253.	263.
19127	237.	229.	239.	244.	254.	244.	250.	250.	255.	258.	265.	266.	273.	261.	270.	273.
19128	232.	234.	240.	240.	245.	246.	243.	242.	245.	250.	254.	259.	260.	258.	264.	270.
19129	221.	220.	223.	224.	228.	225.	227.	234.	228.	229.	234.	238.	241.	229.	237.	246.
19130	243.	240.	242.	249.	252.	249.	249.	252.	250.	253.	256.	262.	258.	256.	261.	269.
19131	217.	226.	230.	232.	235.	233.	234.	231.	233.	231.	239.	240.	243.	238.	246.	235.
19132	225.	234.	240.	233.	234.	245.	240.	237.	233.	241.	247.	248.	240.	245.	245.	254.
19133	226.	227.	226.	233.	233.	238.	235.	234.	241.	245.	246.	249.	253.	257.	252.	
19134	234.	235.	230.	234.	245.	248.	238.	240.	244.	247.	244.	250.	262.	260.	255.	
19135	232.	229.	230.	236.	246.	250.	241.	239.	242.	251.	255.	258.	259.	264.	264.	267.
19136	232.	230.	236.	239.	247.	238.	244.	249.	247.	247.	253.	260.	265.	253.	265.	269.
19137	223.	220.	223.	224.	228.	224.	225.	223.	223.	228.	232.	235.	235.	232.	228.	
19138	233.	233.	239.	240.	247.	246.	248.	251.	246.	253.	254.	262.	271.	263.	266.	265.
19139	227.	226.	224.	228.	235.	234.	230.	234.	234.	237.	238.	239.	249.	248.	247.	
19140	229.	228.	233.	236.	239.	236.	240.	241.	236.	240.	246.	250.	256.	250.	260.	263.
19141	224.	230.	228.	225.	229.	232.	231.	230.	231.	229.	235.	240.	225.	236.	230.	225.
19142	244.	244.	253.	255.	260.	260.	261.	262.	263.	267.	267.	276.	282.	273.	282.	273.
19143	239.	238.	243.	254.	261.	259.	262.	264.	260.	270.	276.	279.	290.	280.	282.	290.
19144	237.	240.	246.	250.	257.	258.	248.	252.	253.	248.	253.	263.	271.	271.	264.	271.
19145	234.	227.	228.	231.	239.	231.	234.	229.	236.	235.	239.	240.	243.	240.	244.	245.
19146	236.	235.	236.	239.	242.	241.	240.	236.	239.	243.	228.	243.	249.	246.	236.	249.
19147	227.	232.	227.	226.	237.	239.	235.	232.	234.	238.	239.	241.	246.	245.	243.	
19148	240.	234.	240.	244.	248.	243.	250.	258.	251.	255.	259.	266.	266.	262.	268.	263.

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Last value recorded before cohabitation.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B26 (PAGE 4): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAY	17	18	19
RAT #	DOSAGE GROUP II		0.01 MG/KG/DAY
19125	253.		
19126	271.	266.	279.
19127	278.		
19128	274.		
19129	249.	246.	250.
19130	272.		
19131	243.		
19132			
19133			
19134			
19135			
19136	267.		
19137			
19138	273.	281.	282.
19139			
19140	256.		
19141	237.	240.	239.
19142	280.	278.	277.
19143			
19144	278.	277.	
19145	242.		
19146	251.	248.	245.
19147			
19148	264.		

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B26 (PAGE 5): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15a	16
RAT #	DOSAGE GROUP III				0.1 MG/KG/DAY											
19149	222.	228.	225.	228.	238.	238.	231.	232.	235.	235.	235.	242.	251.	248.	244.	254.
19150	246.	242.	249.	251.	257.	250.	252.	252.	251.	252.	255.	265.	265.	260.	267.	264.
19151	231.	235.	236.	237.	246.	251.	249.	243.	244.	250.	252.	259.	255.	256.	263.	255.
19152	236.	234.	235.	240.	249.	252.	245.	256.	252.	254.	255.	260.	260.	260.	256.	
19153	229.	225.	231.	237.	243.	240.	243.	245.	245.	252.	253.	261.	264.	260.	262.	
19154	240.	238.	231.	241.	250.	248.	241.	252.	251.	253.	248.	253.	258.	259.	240.	246.
19155	227.	225.	220.	224.	230.	230.	224.	230.	229.	231.	229.	234.	230.	229.	222.	
19156	222.	230.	232.	234.	236.	244.	236.	233.	229.	234.	242.	247.	240.	245.	245.	249.
19157	230.	229.	224.	228.	240.	240.	230.	234.	233.	239.	243.	243.	245.	246.	251.	250.
19158	236.	235.	236.	237.	238.	241.	240.	238.	240.	242.	242.	252.	254.	253.	251.	
19159	232.	231.	230.	236.	245.	245.	240.	238.	241.	245.	230.	246.	250.	253.	257.	253.
19160	235.	234.	229.	234.	245.	247.	240.	239.	240.	246.	242.	247.	254.	254.	247.	
19161	227.	225.	228.	235.	244.	240.	242.	239.	238.	238.	244.	248.	254.	250.	250.	251.
19162	234.	239.	241.	245.	248.	252.	250.	246.	248.	256.	253.	262.	262.	267.	271.	271.
19163	229.	227.	223.	230.	240.	241.	235.	230.	241.	243.	241.	243.	253.	256.	252.	254.
19164	241.	247.	246.	254.	253.	246.	247.	243.	245.	244.	249.	251.	258.	245.	258.	255.
19165	231.	230.	226.	233.	242.	246.	239.	244.	241.	242.	243.	254.	263.	256.	249.	
19166	232.	230.	229.	235.	242.	240.	235.	244.	242.	248.	248.	259.	262.	258.	255.	
19167	227.	231.	226.	231.	244.	250.	241.	238.	242.	231.	249.	253.	254.	256.	246.	263.
19168	232.	234.	226.	233.	243.	240.	232.	241.	241.	244.	241.	248.	248.	245.	247.	
19169	228.	232.	232.	236.	242.	243.	244.	244.	240.	247.	250.	253.	261.	259.	260.	256.
19170	235.	236.	237.	236.	243.	246.	243.	243.	240.	245.	247.	254.	253.	252.	257.	253.
19171	224.	226.	226.	227.	229.	230.	232.	229.	233.	233.	239.	244.	248.	244.	245.	245.
19172	235.	234.	226.	236.	241.	240.	234.	237.	235.	238.	231.	242.	246.	238.	231.	

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Last value recorded before cohabitation.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B26 (PAGE 6): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAY	17	18	19
RAT #	DOSAGE GROUP III		0.1 MG/KG/DAY
19149	260.	267.	
19150	270.		
19151	262.		
19152			
19153			
19154	258.	262.	
19155			
19156			
19157	252.		
19158			
19159			
19160			
19161	250.	250.	
19162			
19163	259.	260.	259.
19164	256.		
19165			
19166			
19167	261.		
19168			
19169	256.	258.	263.
19170			
19171	245.		
19172			

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B26 (PAGE 7): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15a	16
RAT #	DOSAGE GROUP IV				1.0 MG/KG/DAY											
19173	225.	225.	223.	224.	234.	233.	228.	226.	230.	230.	231.	234.	240.	240.	237.	241.
19174	247.	246.	252.	252.	263.	258.	260.	258.	258.	261.	263.	274.	276.	268.	274.	267.
19175	219.	223.	227.	225.	222.	229.	230.	222.	223.	229.	232.	230.	224.	232.	236.	240.
19176	240.	236.	243.	247.	251.	248.	250.	255.	247.	253.	260.	268.	269.	260.	256.	
19177	222.	223.	229.	230.	228.	232.	233.	234.	231.	235.	243.	240.	234.	242.	243.	250.
19178	242.	241.	242.	239.	247.	249.	245.	243.	248.	250.	255.	260.	260.	263.	262.	
19179	231.	231.	229.	229.	241.	245.	244.	237.	235.	245.	253.	252.	252.	242.	253.	255.
19180	233.	234.	235.	233.	244.	247.	240.	238.	243.	245.	246.	250.	258.	256.	251.	
19181	223.	225.	221.	221.	230.	236.	232.	222.	230.	238.	238.	240.	248.	246.	248.	
19182	235.	234.	233.	240.	247.	249.	240.	236.	243.	246.	247.	250.	258.	253.	248.	256.
19183	231.	232.	232.	236.	245.	246.	240.	246.	246.	250.	249.	255.	259.	258.	255.	260.
19184	246.	238.	250.	246.	262.	258.	260.	262.	262.	266.	273.	277.	280.	275.	283.	286.
19185	226.	220.	226.	227.	230.	227.	227.	229.	226.	225.	231.	232.	231.	230.	239.	242.
19186	236.	239.	243.	244.	249.	256.	250.	245.	245.	252.	249.	259.	260.	263.	263.	264.
19187	225.	223.	224.	226.	230.	228.	230.	235.	229.	233.	242.	247.	244.	238.	247.	251.
19188	228.	228.	230.	233.	238.	237.	234.	236.	235.	234.	238.	241.	242.	237.	240.	247.
19189	225.	225.	230.	231.	238.	239.	240.	249.	240.	245.	252.	254.	255.	251.	253.	
19190	247.	251.	253.	248.	247.	253.	255.	256.	253.	260.	263.	267.	254.	265.	267.	276.
19191	226.	232.	233.	232.	235.	240.	241.	238.	240.	248.	249.	250.	249.	254.	254.	255.
19192	238.	233.	231.	234.	243.	250.	238.	235.	242.	245.	247.	251.	249.	249.	252.	256.
19193	227.	228.	228.	231.	235.	232.	237.	242.	238.	227.	236.	241.	242.	243.	240.	
19194	236.	238.	234.	243.	252.	250.	244.	256.	254.	258.	256.	255.	264.	260.	267.	260.
19195	226.	228.	226.	233.	241.	243.	234.	236.	239.	239.	241.	246.	254.	246.	237.	250.
19196	241.	244.	251.	250.	254.	249.	249.	244.	250.	250.	250.	254.	257.	251.	255.	260.

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Last value recorded before cohabitation.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B26 (PAGE 8): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAY	17	18	19
RAT #	DOSAGE GROUP IV		1.0 MG/KG/DAY
19173	241.	237.	
19174	270.		
19175			
19176			
19177			
19178			
19179	259.	266.	
19180			
19181			
19182	260.	266.	
19183	268.	272.	272.
19184	290.		
19185	240.		
19186			
19187	255.		
19188	245.		
19189			
19190			
19191			
19192	252.	260.	266.
19193			
19194	256.	263.	268.
19195	258.	260.	249.
19196	256.		

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).



PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B26 (PAGE 9): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAY	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15a	16
RAT #	DOSAGE GROUP V 30.0 MG/KG/DAY															
19197	243.	233.	243.	240.	247.	236.	243.	242.	241.	238.	241.	246.	244.	241.	246.	253.
19198	244.	241.	238.	242.	252.	252.	246.	248.	253.	260.	261.	264.	269.	273.	267.	
19199	234.	232.	239.	239.	248.	244.	246.	254.	249.	250.	254.	262.	265.	260.	265.	269.
19200	236.	237.	243.	244.	244.	251.	254.	255.	255.	260.	265.	268.	265.	269.	271.	276.
19201	218.	221.	215.	221.	231.	230.	225.	233.	232.	236.	235.	245.	252.	250.	250.	242.
19202	247.	246.	251.	253.	259.	262.	255.	255.	265.	270.	270.	273.	282.	285.	282.	
19203	228.	223.	233.	236.	244.	239.	242.	242.	243.	244.	249.	257.	257.	250.	256.	263.
19204	238.	240.	244.	248.	252.	255.	256.	254.	254.	262.	260.	273.	270.	266.	272.	289.
19205	226.	225.	233.	234.	239.	238.	241.	243.	237.	242.	246.	249.	251.	242.	254.	258.
19206	241.	242.	246.	250.	256.	257.	258.	255.	258.	263.	266.	274.	276.	274.	276.	280.
19207	234.	229.	237.	240.	244.	236.	240.	248.	241.	242.	246.	254.	256.	248.	255.	256.
19208	230.	235.	238.	237.	242.	242.	244.	246.	244.	250.	253.	259.	261.	261.	258.	269.
19209	224.	223.	219.	223.	227.	228.	220.	226.	229.	228.	229.	234.	238.	242.	232.	244.
19210	242.	241.	245.	244.	252.	256.	245.	250.	250.	254.	254.	254.	258.	253.	253.	
19211	232.	240.	236.	237.	247.	253.	247.	250.	251.	257.	252.	259.	265.	264.	266.	
19212	231.	234.	235.	238.	239.	246.	243.	245.	241.	251.	253.	257.	256.	261.	263.	266.
19213	220.	232.	238.	240.	238.	248.	250.	251.	250.	256.	259.	260.	250.	258.	263.	268.
19214	241.	244.	241.	242.	253.	256.	255.	258.	256.	261.	267.	273.	272.	268.	283.	278.
19215	235.	232.	236.	241.	245.	246.	241.	243.	245.	252.	255.	260.	266.	265.	255.	
19216	232.	232.	234.	233.	242.	246.	245.	244.	249.	253.	252.	256.	263.	265.	269.	
19217	225.	225.	217.	226.	233.	233.	223.	233.	232.	233.	232.	239.	245.	236.	228.	245.
19218	233.	232.	227.	230.	237.	238.	231.	233.	237.	241.	239.	238.	242.	244.	240.	
19219	231.	230.	233.	235.	244.	241.	233.	240.	243.	245.	243.	246.	258.	260.	260.	256.
19220	236.	244.	248.	248.	252.	255.	257.	260.	253.	262.	266.	268.	260.	268.	271.	272.

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Last value recorded before cohabitation.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B26 (PAGE 10): BODY WEIGHTS - PRECOHABITATION - INDIVIDUAL DATA - PART D

RAT #	DAY			DOSAGE GROUP V	30.0 MG/KG/DAY
	17	18	19		
19197	250.				
19198					
19199	270.				
19200					
19201	255.	262.			
19202					
19203	258.	269.			
19204	279.				
19205	253.				
19206	278.				
19207	255.				
19208					
19209	249.	255.			
19210					
19211					
19212					
19213					
19214	288.	293.			
19215					
19216					
19217	250.	251.			
19218					
19219					
19220					

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B27 (PAGE 1): MATERNAL BODY WEIGHTS AND GRAVID UTERINE WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY		DAY	0	1	2	3	4	5	6	7	8	9	10	11	12
STATUS															
RAT #		DOSAGE GROUP I													
		0 (CARRIER) MG/KG/DAY													
19101 P		259.	268.	278.	283.	289.	285.	292.	296.	300.	304.	307.	319.	322.	
19102 P		279.	287.	298.	299.	300.	315.	318.	316.	323.	320.	326.	332.	353.	
19103 P		261.	276.	277.	280.	277.	286.	290.	294.	292.	294.	301.	310.	308.	
19104 P		253.	258.	266.	266.	268.	275.	277.	271.	280.	283.	289.	296.	314.	
19105 P		268.	272.	277.	282.	287.	291.	297.	293.	298.	310.	311.	322.	326.	
19107 P		247.	261.	268.	268.	273.	279.	281.	280.	289.	290.	273.	303.	310.	
19108 P		236.	246.	252.	254.	259.	265.	264.	269.	270.	277.	284.	293.	295.	
19109 P		246.	251.	256.	257.	265.	273.	272.	277.	283.	287.	293.	307.	308.	
19110 P		263.	273.	280.	280.	284.	291.	296.	292.	296.	297.	301.	311.	324.	
19111 P		268.	284.	289.	292.	300.	309.	303.	305.	322.	309.	320.	319.	336.	
19112 P		257.	273.	280.	284.	292.	295.	301.	300.	305.	305.	307.	321.	326.	
19113 P		266.	273.	280.	278.	291.	296.	295.	303.	304.	302.	308.	314.	328.	
19114 P		266.	283.	280.	290.	300.	301.	292.	295.	291.	297.	307.	319.	322.	
19115 P		287.	297.	300.	302.	314.	315.	310.	307.	312.	319.	327.	343.	348.	
19116 P		230.	247.	252.	256.	261.	269.	269.	265.	273.	275.	279.	292.	299.	
19117 P		280.	290.	298.	304.	307.	303.	308.	310.	318.	314.	322.	326.	338.	
19119 P		263.	274.	276.	277.	285.	287.	291.	299.	296.	305.	316.	328.	328.	
19120 NP		246.	260.	270.	269.	274.	286.	296.	289.	298.	293.	297.	302.	315.	
19123 P		265.	277.	284.	283.	288.	289.	295.	300.	291.	302.	305.	310.	311.	
19124 P		268.	272.	282.	290.	287.	302.	305.	311.	309.	309.	312.	317.	326.	

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAY = DAY OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B27 (PAGE 2): MATERNAL BODY WEIGHTS AND GRAVID UTERINE WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY STATUS	DAY 13	14	15	16	17	18	19	20	21	GRAVID UTERINE WEIGHTS (G)
RAT #	DOSAGE GROUP I				0 (CARRIER) MG/KG/DAY					
19101 P	321.	330.	340.	351.	368.	384.	397.	413.	440.	113.34
19102 P	349.	355.	362.	380.	383.	400.	424.	431.	453.	95.93
19103 P	312.	310.	320.	326.	339.	356.	367.	381.	407.	102.66
19104 P	311.	313.	321.	328.	339.	354.	378.	382.	401.	92.60
19105 P	324.	332.	343.	352.	360.	384.	396.	413.	433.	101.86
19107 P	323.	323.	336.	343.	356.	367.	386.	398.	414.	91.77
19108 P	297.	302.	309.	313.	327.	346.	354.	371.	385.	97.06
19109 P	309.	316.	324.	330.	342.	359.	370.	384.	403.	98.64
19110 P	324.	322.	332.	338.	351.	369.	390.	403.	425.	117.82
19111 P	334.	336.	338.	347.	364.	377.	394.	404.	431.	96.76
19112 P	329.	333.	346.	355.	368.	391.	409.	425.	445.	107.66
19113 P	338.	341.	356.	363.	364.	387.	412.	420.	452.	109.63
19114 P	328.	333.	336.	341.	355.	374.	383.	405.	422.	91.75
19115 P	345.	354.	361.	366.	390.	416.	420.	448.	467.	120.81
19116 P	303.	306.	318.	322.	334.	347.	369.	377.	395.	104.88
19117 P	340.	345.	347.	357.	366.	384.	404.	406.	423.	98.51
19119 P	334.	338.	352.	354.	371.	394.	404.	428.	448.	119.46
19120 NP	318.	321.	326.	314.	302.	305.	308.	300.	291.	-----
19123 P	327.	326.	330.	346.	350.	365.	378.	396.	415.	99.44
19124 P	344.	354.	357.	361.	377.	374.	396.	414.	437.	106.18

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAY = DAY OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B27 (PAGE 3): MATERNAL BODY WEIGHTS AND GRAVID UTERINE WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY STATUS	DAY	0	1	2	3	4	5	6	7	8	9	10	11	12
RAT #	DOSAGE GROUP II	0.01 MG/KG/DAY												
19125 P		257.	262.	265.	270.	272.	270.	271.	273.	272.	276.	280.	304.	302.
19127 NP		273.	289.	292.	303.	315.	318.	324.	327.	329.	334.	336.	352.	351.
19128 P		262.	271.	266.	276.	275.	280.	277.	284.	292.	308.	311.	330.	330.
19130 P		267.	281.	280.	290.	294.	294.	296.	307.	305.	315.	319.	330.	334.
19131 P		254.	252.	257.	259.	266.	272.	270.	278.	275.	279.	287.	301.	304.
19132 P		253.	259.	267.	266.	271.	281.	284.	279.	285.	286.	290.	296.	305.
19133 P		243.	259.	270.	272.	273.	276.	286.	296.	290.	297.	302.	310.	315.
19134 P		253.	262.	270.	273.	272.	273.	287.	290.	283.	291.	292.	294.	306.
19135 P		269.	284.	283.	289.	295.	305.	298.	305.	302.	308.	316.	328.	339.
19136 P		250.	265.	269.	274.	291.	285.	290.	292.	295.	302.	304.	318.	313.
19137 P		231.	240.	248.	252.	257.	264.	269.	273.	271.	279.	279.	290.	294.
19139 P		246.	254.	270.	273.	271.	277.	288.	291.	284.	292.	286.	295.	302.
19140 P		254.	266.	269.	286.	302.	294.	293.	304.	296.	306.	305.	330.	330.
19141 P		250.	272.	261.	266.	265.	270.	272.	275.	286.	291.	288.	295.	305.
19143 P		295.	289.	303.	306.	303.	313.	317.	312.	321.	322.	323.	333.	349.
19144 P		271.	282.	288.	293.	294.	290.	297.	292.	296.	306.	320.	325.	331.
19145 P		241.	248.	254.	257.	259.	259.	263.	265.	270.	270.	278.	287.	292.
19146 P		247.	254.	256.	258.	271.	268.	273.	277.	281.	284.	288.	302.	304.
19147 P		248.	256.	263.	263.	266.	265.	273.	273.	280.	278.	282.	284.	292.
19148 P		264.	271.	282.	293.	290.	297.	291.	298.	296.	296.	301.	305.	304.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAY = DAY OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B27 (PAGE 4): MATERNAL BODY WEIGHTS AND GRAVID UTERINE WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY STATUS	DAY 13	14	15	16	17	18	19	20	21	GRAVID UTERINE WEIGHTS (G)
RAT #	DOSAGE GROUP II		0.01 MG/KG/DAY							
19125 P	305.	309.	323.	320.	338.	357.	364.	383.	406.	99.26
19127 NP	356.	350.	350.	334.	337.	347.	330.	324.	336.	-----
19128 P	336.	343.	348.	354.	372.	387.	405.	423.	447.	119.53
19130 P	330.	339.	347.	348.	358.	379.	389.	409.	430.	99.99
19131 P	314.	322.	325.	325.	338.	357.	357.	384.	396.	76.09
19132 P	308.	308.	317.	324.	337.	353.	372.	380.	408.	100.93
19133 P	329.	326.	333.	343.	357.	370.	377.	401.	413.	96.38
19134 P	318.	319.	328.	342.	347.	354.	365.	391.	410.	90.27
19135 P	338.	343.	353.	361.	366.	378.	406.	407.	436.	95.90
19136 P	320.	328.	332.	330.	341.	364.	370.	385.	403.	97.97
19137 P	304.	299.	306.	318.	326.	335.	353.	364.	371.	73.40
19139 P	307.	307.	312.	324.	337.	345.	362.	386.	402.	101.33
19140 P	340.	344.	359.	360.	378.	399.	402.	440.	462.	125.76
19141 P	312.	310.	323.	320.	342.	350.	366.	365.	395.	82.56
19143 P	343.	348.	356.	363.	364.	377.	396.	392.	408.	26.34
19144 P	331.	343.	336.	348.	373.	378.	410.	410.	444.	102.86
19145 P	294.	305.	308.	310.	319.	339.	344.	365.	380.	95.01
19146 P	318.	314.	316.	334.	335.	345.	369.	383.	398.	82.00
19147 P	300.	295.	306.	315.	330.	338.	354.	375.	388.	95.40
19148 P	305.	314.	319.	325.	335.	354.	358.	381.	388.	74.12

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAY = DAY OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B27 (PAGE 5): MATERNAL BODY WEIGHTS AND GRAVID UTERINE WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY		DAY 0	1	2	3	4	5	6	7	8	9	10	11	12
STATUS	DAY													
RAT #	DOSAGE GROUP III	0.1 MG/KG/DAY												
19150 P		267.	276.	280.	292.	295.	297.	294.	300.	304.	308.	320.	331.	329.
19151 P		258.	268.	276.	278.	289.	288.	292.	293.	291.	296.	300.	313.	313.
19152 P		243.	263.	262.	276.	277.	276.	287.	287.	291.	297.	298.	299.	306.
19153 NP		253.	277.	286.	287.	290.	300.	309.	310.	298.	309.	308.	309.	309.
19155 P		222.	231.	245.	247.	260.	261.	273.	272.	276.	280.	280.	297.	300.
19156 NP		251.	261.	262.	268.	265.	275.	274.	271.	277.	279.	286.	292.	294.
19157 P		250.	263.	277.	283.	288.	286.	288.	300.	292.	299.	302.	312.	324.
19158 P		249.	260.	268.	275.	273.	279.	288.	288.	290.	297.	296.	307.	317.
19159 P		247.	261.	267.	268.	275.	284.	281.	287.	289.	289.	290.	304.	314.
19160 P		247.	254.	264.	266.	268.	276.	279.	280.	285.	290.	294.	299.	303.
19161 P		234.	251.	266.	266.	270.	270.	281.	279.	287.	293.	303.	306.	308.
19162 P		265.	279.	289.	287.	296.	300.	305.	308.	313.	316.	313.	320.	323.
19164 P		269.	265.	273.	284.	288.	290.	295.	296.	296.	304.	307.	317.	325.
19165 P		246.	260.	271.	275.	271.	269.	278.	280.	272.	284.	283.	301.	297.
19166 NP		256.	272.	278.	291.	295.	309.	314.	319.	313.	322.	326.	325.	329.
19167 P		251.	265.	268.	272.	274.	281.	284.	289.	291.	303.	310.	329.	331.
19168 P		249.	261.	268.	279.	279.	286.	289.	291.	293.	297.	306.	313.	311.
19170 P		258.	272.	274.	279.	280.	288.	294.	291.	294.	295.	297.	306.	313.
19171 P		256.	261.	268.	265.	272.	280.	280.	285.	283.	288.	294.	301.	307.
19172 P		226.	229.	239.	245.	247.	251.	256.	264.	261.	262.	269.	280.	279.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAY = DAY OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B27 (PAGE 6): MATERNAL BODY WEIGHTS AND GRAVID UTERINE WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY										GRAVID UTERINE	
STATUS	DAY 13	14	15	16	17	18	19	20	21	WEIGHTS (G)	
RAT #	DOSAGE GROUP III				0.1 MG/KG/DAY						
19150 P	331.	334.	338.	345.	356.	373.	389.	410.	431.	106.07	
19151 P	314.	324.	328.	328.	337.	348.	356.	363.	381.	47.13	
19152 P	323.	317.	331.	341.	353.	364.	380.	399.	424.	101.90	
19153 NP	308.	298.	307.	318.	322.	323.	328.	339.	340.	-----	
19155 P	317.	314.	320.	328.	337.	339.	353.	376.	398.	75.91	
19156 NP	289.	290.	287.	284.	276.	273.	278.	273.	282.	-----	
19157 P	325.	330.	331.	332.	351.	369.	374.	392.	403.	82.29	
19158 P	330.	334.	344.	359.	379.	387.	404.	426.	448.	116.01	
19159 P	317.	324.	336.	346.	354.	369.	392.	389.	417.	98.15	
19160 P	315.	311.	319.	329.	343.	346.	352.	376.	394.	75.75	
19161 P	315.	316.	316.	329.	341.	356.	369.	381.	397.	107.20	
19162 P	331.	334.	343.	357.	364.	381.	398.	413.	429.	115.60	
19164 P	330.	331.	342.	352.	361.	384.	400.	416.	439.	108.36	
19165 P	316.	309.	323.	336.	348.	362.	382.	394.	418.	107.97	
19166 NP	331.	316.	315.	314.	301.	299.	303.	302.	302.	-----	
19167 P	338.	345.	350.	351.	366.	389.	402.	424.	450.	110.56	
19168 P	319.	327.	334.	341.	357.	365.	383.	399.	414.	77.40	
19170 P	315.	321.	323.	335.	345.	358.	376.	389.	405.	98.22	
19171 P	307.	320.	329.	335.	350.	370.	377.	396.	418.	100.11	
19172 P	286.	287.	294.	296.	306.	304.	308.	317.	327.	22.08	

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAY = DAY OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).



PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B27 (PAGE 7): MATERNAL BODY WEIGHTS AND GRAVID UTERINE WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY													
STATUS	DAY 0	1	2	3	4	5	6	7	8	9	10	11	12
DOSAGE GROUP IV													
RAT #	1.0 MG/KG/DAY												
19173 P	238.	244.	253.	261.	262.	262.	265.	269.	269.	274.	290.	293.	299.
19174 P	275.	290.	291.	290.	294.	296.	300.	297.	298.	304.	317.	333.	336.
19175 P	243.	251.	264.	264.	270.	279.	280.	281.	284.	286.	292.	303.	310.
19176 P	253.	271.	282.	284.	286.	296.	299.	285.	285.	294.	288.	311.	308.
19177 P	252.	260.	275.	270.	277.	284.	287.	287.	293.	292.	296.	302.	312.
19178 P	262.	272.	280.	289.	290.	294.	302.	297.	300.	305.	303.	311.	325.
19179 P	249.	261.	277.	282.	279.	279.	287.	283.	296.	297.	309.	308.	321.
19180 P	257.	270.	266.	283.	276.	286.	289.	295.	291.	292.	288.	296.	306.
19181 P	240.	255.	264.	263.	264.	274.	281.	282.	284.	287.	298.	304.	316.
19182 P	257.	264.	275.	280.	285.	288.	295.	293.	298.	308.	316.	318.	326.
19184 P	288.	300.	308.	312.	319.	318.	320.	321.	328.	337.	337.	348.	354.
19185 P	240.	250.	259.	262.	250.	271.	267.	270.	271.	274.	283.	296.	299.
19186 P	270.	270.	281.	276.	270.	282.	294.	291.	297.	300.	315.	322.	335.
19187 P	253.	266.	265.	272.	280.	281.	280.	288.	290.	292.	304.	315.	312.
19188 P	255.	258.	267.	268.	270.	270.	273.	273.	278.	287.	292.	300.	301.
19189 P	246.	258.	269.	277.	280.	281.	292.	296.	294.	303.	299.	302.	307.
19190 P	281.	291.	300.	309.	313.	318.	320.	324.	327.	331.	331.	342.	348.
19191 P	253.	269.	273.	275.	269.	282.	287.	284.	295.	294.	294.	300.	316.
19193 P	232.	243.	253.	254.	258.	262.	265.	267.	269.	274.	277.	283.	288.
19196 P	252.	263.	262.	265.	271.	274.	276.	280.	281.	287.	292.	307.	308.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAY = DAY OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAY = DAY OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B27 (PAGE 8): MATERNAL BODY WEIGHTS AND GRAVID UTERINE WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY STATUS	DAY 13	14	15	16	17	18	19	20	21	GRAVID UTERINE WEIGHTS (G)
RAT #	DOSAGE GROUP IV				1.0 MG/KG/DAY					
19173 P	302.	308.	316.	318.	340.	344.	368.	389.	409.	111.21
19174 P	349.	351.	359.	363.	382.	410.	423.	454.	473.	134.97
19175 P	311.	323.	327.	344.	350.	363.	387.	394.	417.	122.23
19176 P	332.	323.	333.	338.	363.	366.	376.	393.	410.	90.71
19177 P	314.	318.	326.	334.	345.	355.	381.	386.	402.	75.80
19178 P	332.	332.	345.	360.	370.	380.	388.	415.	434.	106.10
19179 P	324.	330.	329.	338.	351.	360.	389.	400.	421.	102.49
19180 P	323.	324.	330.	340.	360.	378.	391.	412.	431.	128.05
19181 P	326.	324.	334.	341.	363.	374.	389.	413.	431.	110.96
19182 P	331.	335.	334.	344.	367.	377.	397.	410.	426.	109.67
19184 P	357.	370.	373.	382.	394.	414.	432.	458.	479.	117.67
19185 P	302.	307.	314.	313.	336.	358.	373.	398.	422.	115.82
19186 P	338.	340.	350.	357.	364.	381.	403.	421.	447.	114.95
19187 P	317.	322.	326.	330.	340.	359.	368.	386.	411.	98.44
19188 P	306.	313.	320.	318.	332.	353.	360.	379.	404.	97.06
19189 P	321.	319.	321.	324.	329.	340.	344.	354.	363.	35.76
19190 P	361.	364.	375.	387.	410.	433.	446.	468.	493.	139.64
19191 P	323.	326.	335.	348.	361.	378.	393.	410.	425.	116.28
19193 P	296.	298.	306.	313.	326.	340.	353.	372.	387.	95.26
19196 P	314.	324.	322.	328.	338.	359.	369.	389.	408.	94.32

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAY = DAY OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B27 (PAGE 9): MATERNAL BODY WEIGHTS AND GRAVID UTERINE WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY STATUS		DAY	0	1	2	3	4	5	6	7	8	9	10	11	12
RAT #		DOSAGE GROUP V		30.0 MG/KG/DAY											
19197	P	251.	256.	260.	263.	273.	275.	275.	278.	281.	280.	292.	306.	311.	
19198	P	263.	280.	286.	290.	287.	291.	286.	293.	291.	297.	296.	304.	315.	
19199	P	274.	285.	292.	298.	292.	286.	291.	296.	299.	300.	311.	323.	327.	
19200	P	278.	289.	293.	296.	308.	314.	308.	311.	318.	318.	326.	333.	343.	
19201	P	256.	267.	273.	282.	281.	283.	285.	284.	291.	296.	308.	316.	317.	
19202	P	281.	292.	297.	305.	302.	303.	320.	320.	321.	330.	323.	335.	341.	
19205	P	260.	278.	277.	282.	288.	294.	295.	299.	298.	303.	305.	312.	314.	
19206	P	274.	281.	286.	295.	295.	299.	304.	304.	311.	321.	325.	334.	338.	
19207	P	249.	257.	270.	279.	291.	291.	290.	298.	296.	302.	305.	315.	320.	
19208	P	265.	278.	290.	291.	302.	311.	313.	313.	315.	315.	321.	320.	327.	
19211	P	264.	269.	284.	280.	286.	294.	302.	307.	305.	315.	307.	316.	323.	
19212	P	255.	277.	278.	286.	293.	300.	303.	300.	310.	310.	317.	325.	341.	
19213	P	260.	278.	286.	293.	300.	302.	305.	306.	318.	319.	326.	332.	338.	
19216	P	263.	269.	276.	284.	286.	286.	295.	301.	291.	300.	300.	308.	309.	
19219	P	255.	270.	272.	289.	293.	291.	293.	294.	300.	299.	306.	312.	323.	
19220	P	273.	286.	285.	289.	290.	295.	290.	292.	295.	295.	307.	316.	326.	

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAY = DAY OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B27 (PAGE 10): MATERNAL BODY WEIGHTS AND GRAVID UTERINE WEIGHTS - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY STATUS	DAY 13	14	15	16	17	18	19	20	21	GRAVID UTERINE WEIGHTS (G)
RAT #	DOSAGE GROUP V				30.0 MG/KG/DAY					
19197 P	315.	318.	328.	332.	340.	366.	369.	390.	409.	102.60
19198 P	317.	321.	333.	336.	348.	361.	373.	390.	407.	86.40
19199 P	326.	338.	341.	347.	361.	383.	394.	404.	397.	90.63
19200 P	345.	347.	354.	357.	369.	378.	402.	408.	440.	83.63
19201 P	321.	330.	326.	338.	362.	369.	389.	410.	425.	95.61
19202 P	355.	361.	362.	370.	386.	387.	402.	416.	434.	65.70
19205 P	319.	332.	336.	340.	352.	381.	388.	415.	434.	93.32
19206 P	340.	347.	350.	354.	366.	383.	392.	410.	427.	87.26
19207 P	323.	328.	338.	341.	354.	368.	376.	399.	421.	89.55
19208 P	330.	338.	340.	359.	363.	376.	403.	408.	431.	96.33
19211 P	324.	332.	342.	358.	369.	396.	405.	427.	449.	107.47
19212 P	342.	348.	355.	372.	380.	397.	418.	429.	462.	106.67
19213 P	345.	351.	360.	367.	383.	398.	413.	428.	456.	109.85
19216 P	318.	324.	328.	340.	352.	358.	372.	385.	405.	76.73
19219 P	325.	328.	339.	349.	359.	376.	397.	406.	431.	101.10
19220 P	330.	335.	340.	350.	351.	362.	388.	392.	415.	89.21

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAY = DAY OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B28 (PAGE 1): WATER CONSUMPTION VALUES - PRECOHABITATION - INDIVIDUAL DATA - PART D

RAT #	DAYS														14- 15a													
	DOSAGE GROUP I														0 (CARRIER) MG/KG/DAY													
	1-	2	2-	3	3-	4	4-	5	5-	6	6-	7	7-	8	8-	9	9-	10	10-	11	11-	12	12-	13	13-	14	14-	15a
19101	21.	29.	29.	28.	25.	22.	22.	24.	27.	27.	27.	27.	27.	27.	27.	27.	27.	27.	27.	27.	27.	27.	27.	27.	27.	27.	27.	27.
19102	29.	30.	30.	23.	19.	27.	27.	30.	17.	23.	25.	25.	27.	23.	32.	20.	20.	28.	21.	24.	23.	24.	21.	28.	20.	25.	26.	26.
19103	25.	20.	20.	25.	42.	35.	35.	38.	38.	32.	26.	26.	27.	38.	37.	27.	27.	41.	28.	27.	24.	27.	41.	28.	30.	28.	30.	30.
19104	26.	28.	28.	25.	18.	27.	27.	27.	26.	18.	23.	23.	26.	18.	23.	23.	23.	20.	19.	24.	24.	20.	24.	19.	24.	24.	24.	24.
19105	32.	38.	38.	36.	33.	31.	31.	35.	39.	33.	24.	24.	31.	33.	33.	24.	24.	34.	19.	27.	34.	41.	27.	36.	27.	36.	36.	36.
19106	33.	35.	35.	33.	27.	23.	23.	33.	32.	29.	3.	3.	2.	32.	32.	3.	3.	32.	26.	32.	32.	32.	32.	26.	25.	25.	25.	
19107	28.	36.	36.	38.	35.	27.	27.	38.	27.	36.	25.	34.	34.	36.	34.	25.	25.	43.	22.	23.	24.	43.	22.	23.	23.	23.	23.	23.
19108	24.	29.	29.	27.	24.	23.	23.	24.	29.	19.	19.	21.	21.	17.	17.	22.	22.	14.	20.	20.	17.	22.	14.	20.	20.	20.	20.	20.
19109	14.	23.	23.	21.	19.	15.	15.	18.	23.	18.	15.	15.	18.	23.	18.	15.	15.	17.	16.	16.	21.	15.	17.	16.	16.	16.	16.	16.
19110	21.	26.	26.	9.	27.	22.	22.	22.	19.	4.	33.	22.	22.	20.	20.	24.	24.	23.	24.	23.	20.	24.	23.	24.	23.	24.	24.	24.
19111	36.	33.	33.	28.	27.	39.	39.	33.	28.	10.	21.	21.	35.	28.	42.	36.	32.	32.	32.	32.	28.	42.	36.	32.	32.	32.	32.	32.
19112	28.	27.	27.	28.	28.	28.	28.	26.	32.	26.	31.	27.	27.	26.	39.	29.	29.	17.	17.	17.	26.	39.	29.	29.	29.	29.	29.	29.
19113	34.	33.	33.	30.	25.	34.	34.	32.	33.	24.	27.	27.	28.	25.	25.	25.	25.	28.	28.	28.	25.	25.	29.	28.	28.	28.	28.	28.
19114	27.	30.	30.	35.	30.	29.	29.	33.	29.	28.	23.	27.	27.	23.	27.	31.	23.	23.	23.	23.	27.	31.	23.	23.	23.	23.	23.	23.
19115	26.	34.	34.	33.	27.	24.	24.	29.	30.	29.	30.	30.	30.	29.	33.	27.	27.	27.	27.	27.	30.	33.	27.	27.	27.	27.	27.	27.
19116	26.	31.	31.	25.	20.	25.	25.	25.	25.	11.	23.	25.	25.	11.	23.	25.	25.	24.	22.	22.	20.	21.	24.	22.	22.	22.	22.	22.
19117	21.	27.	27.	27.	25.	23.	23.	b	28.	15.	21.	26.	26.	15.	21.	26.	26.	19.	19.	19.	25.	34.	26.	19.	19.	19.	19.	19.
19118	35.	30.	30.	36.	34.	36.	36.	31.	35.	4.	2.	2.	1.	35.	4.	2.	2.	17.	17.	17.	1.	17.	23.	17.	17.	17.	17.	17.
19119	21.	26.	26.	28.	26.	22.	22.	26.	32.	20.	19.	22.	22.	32.	20.	31.	20.	23.	23.	23.	20.	31.	20.	23.	23.	23.	23.	23.
19120	40.	42.	42.	30.	38.	40.	40.	43.	23.	36.	39.	32.	32.	36.	42.	37.	39.	39.	39.	39.	28.	42.	37.	39.	39.	39.	39.	39.
19121	28.	16.	16.	35.	34.	33.	33.	24.	33.	27.	26.	22.	22.	33.	21.	2.	2.	21.	2.	21.	22.	21.	2.	2.	2.	2.	2.	2.
19122	35.	37.	37.	30.	22.	29.	29.	37.	28.	26.	2.	41.	26.	26.	24.	28.	24.	24.	26.	26.	25.	28.	24.	26.	26.	26.	26.	26.
19123	28.	31.	31.	26.	27.	29.	29.	16.	27.	2.	1.	3.	44.	30.	27.	30.	30.	30.	30.	30.	1.	3.	44.	30.	27.	27.	27.	27.
19124	37.	36.	36.	31.	35.	39.	39.	38.	36.	35.	34.	31.	31.	36.	35.	37.	37.	38.	38.	38.	30.	37.	38.	38.	38.	38.	38.	38.

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Last value recorded before cohobitation.

b. Value not tabulated due to spillage or presumed spillage.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B28 (PAGE 2): WATER CONSUMPTION VALUES - PRECOHABITATION - INDIVIDUAL DATA - PART D

RAT #	DAYS															0.01 MG/KG/DAY															
	DOSAGE GROUP II																														
19125	22.	30.	37.	25.	27.	28.	36.	27.	22.	25.	30.	28.	26.	27.																	
19126	24.	19.	26.	24.	23.	18.	28.	21.	19.	21.	24.	25.	23.	21.																	
19127	25.	36.	37.	32.	24.	38.	43.	33.	27.	35.	33.	37.	26.	38.																	
19128	26.	30.	28.	28.	26.	29.	35.	24.	23.	26.	24.	26.	23.	24.																	
19129	29.	34.	40.	34.	26.	37.	37.	18.	21.	40.	32.	41.	28.	35.																	
19130	18.	26.	30.	20.	20.	17.	28.	2.	1.	12.	22.	25.	25.	27.																	
19131	37.	38.	39.	28.	30.	36.	33.	32.	24.	30.	27.	32.	27.	28.																	
19132	31.	38.	33.	20.	32.	35.	40.	25.	32.	37.	32.	30.	43.	36.																	
19133	28.	24.	32.	24.	b	b	29.	28.	28.	25.	23.	34.	30.	26.																	
19134	37.	26.	34.	33.	34.	28.	34.	30.	30.	23.	27.	43.	35.	21.																	
19135	26.	27.	28.	27.	26.	22.	23.	3.	14.	25.	21.	26.	26.	27.																	
19136	33.	36.	b	b	b	27.	53.	7.	17.	9.	56.	31.	28.	30.																	
19137	16.	23.	22.	19.	17.	23.	27.	19.	19.	24.	20.	23.	21.	17.																	
19138	30.	39.	35.	28.	32.	32.	37.	31.	31.	32.	24.	38.	28.	32.																	
19139	35.	25.	32.	34.	34.	27.	34.	35.	29.	28.	21.	38.	36.	34.																	
19140	34.	36.	34.	28.	28.	40.	39.	31.	26.	31.	30.	31.	27.	32.																	
19141	31.	29.	23.	25.	29.	28.	28.	17.	21.	26.	22.	22.	27.	25.																	
19142	24.	35.	33.	32.	29.	31.	39.	25.	7.	6.	32.	34.	26.	30.																	
19143	31.	40.	43.	33.	35.	43.	53.	30.	35.	36.	29.	44.	34.	31.																	
19144	45.	51.	54.	48.	46.	31.	40.	33.	25.	24.	41.	39.	35.	28.																	
19145	22.	31.	32.	28.	22.	b	28.	24.	19.	22.	28.	25.	22.	23.																	
19146	36.	45.	41.	34.	35.	40.	41.	16.	31.	2.	38.	36.	35.	32.																	
19147	36.	32.	27.	34.	32.	44.	28.	32.	29.	22.	32.	39.	29.	20.																	
19148	22.	30.	32.	26.	19.	26.	32.	7.	6.	1.	6.	38.	23.	29.																	

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Last value recorded before cohabitation.

b. Value not tabulated due to spillage or presumed spillage.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B28 (PAGE 3): WATER CONSUMPTION VALUES - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAYS	1- 2	2- 3	3- 4	4- 5	5- 6	6- 7	7- 8	8- 9	9- 10	10- 11	11- 12	12- 13	13- 14	14- 15a
RAT #	DOSAGE GROUP III				0.1 MG/KG/DAY									
19149	31.	27.	35.	37.	30.	26.	37.	30.	22.	27.	25.	32.	28.	24.
19150	36.	42.	38.	33.	34.	39.	50.	38.	30.	42.	32.	51.	34.	38.
19151	30.	23.	30.	30.	30.	30.	25.	18.	26.	31.	29.	21.	26.	25.
19152	43.	31.	41.	40.	38.	28.	45.	42.	31.	31.	31.	43.	34.	26.
19153	23.	35.	38.	33.	25.	36.	43.	35.	26.	29.	35.	39.	28.	25.
19154	26.	18.	30.	32.	23.	20.	28.	27.	22.	5.	22.	32.	22.	16.
19155	23.	19.	26.	25.	22.	20.	26.	25.	22.	19.	21.	18.	21.	12.
19156	38.	35.	29.	24.	33.	31.	34.	28.	33.	30.	25.	22.	32.	27.
19157	34.	29.	31.	32.	29.	24.	20.	25.	32.	28.	23.	29.	29.	30.
19158	26.	28.	25.	23.	24.	29.	32.	22.	22.	24.	24.	28.	24.	23.
19159	49.	38.	b	b	b	b	b	b	19.	1.	30.	b	42.	36.
19160	25.	20.	27.	27.	25.	21.	29.	23.	26.	17.	27.	30.	25.	18.
19161	47.	49.	41.	39.	42.	44.	49.	35.	38.	38.	34.	49.	41.	38.
19162	34.	41.	42.	32.	43.	49.	33.	4.	27.	6.	37.	36.	37.	36.
19163	30.	27.	33.	30.	31.	33.	38.	32.	32.	33.	27.	38.	32.	25.
19164	44.	43.	39.	29.	28.	28.	32.	20.	21.	28.	22.	31.	21.	32.
19165	34.	26.	38.	35.	39.	30.	32.	5.	7.	27.	30.	37.	29.	24.
19166	39.	28.	42.	42.	b	48.	b	9.	5.	3.	40.	b	43.	27.
19167	23.	19.	26.	24.	23.	21.	21.	21.	2.	26.	20.	26.	24.	5.
19168	32.	26.	29.	33.	31.	21.	29.	25.	22.	23.	22.	28.	24.	24.
19169	42.	43.	b	b	35.	b	29.	16.	24.	24.	23.	36.	28.	27.
19170	27.	30.	27.	26.	29.	27.	31.	14.	24.	27.	25.	28.	27.	29.
19171	35.	36.	30.	26.	32.	35.	33.	1.	5.	28.	27.	35.	24.	27.
19172	24.	16.	25.	22.	22.	17.	22.	17.	17.	8.	17.	25.	15.	13.

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Last value recorded before cohabitation.

b. Value not tabulated due to spillage or presumed spillage.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B28 (PAGE 4): WATER CONSUMPTION VALUES - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAYS	1- 2	2- 3	3- 4	4- 5	5- 6	6- 7	7- 8	8- 9	9- 10	10- 11	11- 12	12- 13	13- 14	14- 15a
RAT #	DOSAGE GROUP IV 1.0 MG/KG/DAY													
19173	26.	25.	31.	33.	26.	27.	33.	26.	19.	21.	23.	37.	26.	30.
19174	26.	36.	35.	31.	22.	32.	33.	27.	19.	35.	30.	34.	22.	27.
19175	24.	25.	21.	18.	24.	24.	22.	16.	21.	23.	20.	21.	23.	24.
19176	44.	b	b	45.	b	b	42.	b	32.	42.	b	b	42.	38.
19177	25.	24.	25.	15.	24.	23.	26.	7.	7.	31.	20.	28.	29.	28.
19178	42.	34.	32.	32.	34.	38.	32.	41.	32.	39.	33.	42.	44.	42.
19179	22.	24.	17.	29.	23.	25.	16.	18.	24.	26.	23.	25.	20.	25.
19180	29.	27.	25.	30.	32.	25.	22.	27.	31.	26.	25.	37.	30.	28.
19181	34.	33.	24.	36.	41.	29.	26.	32.	28.	26.	32.	36.	34.	32.
19182	32.	30.	39.	29.	33.	26.	32.	32.	31.	29.	27.	44.	28.	25.
19183	28.	23.	28.	27.	28.	22.	29.	11.	13.	22.	31.	48.	32.	24.
19184	22.	31.	18.	40.	27.	32.	33.	17.	5.	4.	b	9.	19.	25.
19185	26.	28.	33.	30.	25.	28.	30.	22.	19.	24.	17.	32.	23.	29.
19186	24.	26.	24.	22.	27.	25.	25.	18.	23.	22.	37.	21.	21.	21.
19187	24.	28.	29.	24.	23.	27.	30.	22.	21.	25.	c	32.	24.	b
19188	24.	29.	33.	23.	21.	26.	40.	6.	18.	22.	20.	29.	18.	23.
19189	21.	23.	26.	21.	19.	24.	21.	6.	19.	21.	18.	25.	18.	23.
19190	51.	44.	31.	24.	34.	30.	28.	3.	17.	5.	22.	15.	25.	24.
19191	26.	28.	28.	20.	28.	23.	25.	17.	28.	25.	19.	26.	26.	23.
19192	27.	22.	27.	23.	25.	19.	14.	26.	22.	26.	20.	20.	23.	23.
19193	21.	20.	22.	20.	17.	22.	23.	14.	3.	22.	19.	21.	16.	15.
19194	25.	17.	29.	24.	20.	19.	22.	16.	26.	21.	14.	29.	24.	21.
19195	34.	24.	36.	31.	36.	27.	39.	6.	2.	30.	27.	36.	32.	23.
19196	40.	36.	43.	31.	31.	35.	35.	5.	3.	16.	18.	35.	29.	33.

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

- a. Last value recorded before cohabitation.
- b. Value not tabulated due to spillage or presumed spillage.
- c. Value was incorrectly recorded.



PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B28 (PAGE 5): WATER CONSUMPTION VALUES - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAYS	1- 2	2- 3	3- 4	4- 5	5- 6	6- 7	7- 8	8- 9	9- 10	10- 11	11- 12	12- 13	13- 14	14- 15a
RAT #	DOSAGE GROUP V 30.0 MG/KG/DAY													
19197	21.	27.	23.	24.	15.	26.	24.	21.	14.	19.	20.	18.	18.	23.
19198	29.	21.	29.	29.	29.	20.	32.	30.	29.	28.	21.	38.	30.	24.
19199	24.	32.	35.	30.	19.	27.	30.	28.	18.	28.	27.	33.	20.	27.
19200	30.	34.	34.	18.	33.	27.	33.	29.	25.	25.	26.	32.	28.	31.
19201	33.	21.	35.	31.	29.	25.	34.	4.	16.	30.	26.	37.	31.	29.
19202	25.	25.	30.	22.	25.	22.	25.	15.	12.	13.	21.	29.	28.	26.
19203	21.	30.	29.	27.	26.	30.	31.	25.	26.	29.	24.	34.	19.	31.
19204	31.	37.	36.	35.	40.	37.	37.	28.	32.	34.	29.	46.	33.	33.
19205	26.	38.	36.	32.	30.	34.	35.	22.	26.	30.	23.	36.	22.	29.
19206	24.	30.	30.	29.	29.	33.	24.	29.	25.	25.	35.	33.	25.	28.
19207	22.	32.	26.	37.	26.	33.	34.	19.	13.	22.	28.	35.	25.	25.
19208	37.	44.	37.	30.	41.	34.	32.	32.	38.	35.	32.	43.	39.	36.
19209	25.	24.	35.	28.	27.	23.	27.	21.	20.	21.	21.	30.	25.	17.
19210	29.	27.	29.	28.	26.	23.	30.	24.	23.	20.	25.	32.	21.	21.
19211	31.	35.	27.	30.	33.	37.	30.	21.	13.	6.	32.	31.	29.	27.
19212	26.	25.	31.	21.	30.	27.	26.	16.	23.	22.	20.	31.	25.	26.
19213	30.	29.	30.	20.	33.	36.	28.	2.	7.	20.	18.	20.	25.	22.
19214	31.	37.	31.	35.	40.	38.	31.	11.	29.	35.	27.	43.	26.	34.
19215	b	b	b	b	b	b	b	37.	24.	31.	43.	38.	41.	50.
19216	28.	36.	28.	33.	35.	33.	24.	26.	32.	24.	24.	31.	27.	23.
19217	27.	19.	29.	26.	25.	19.	27.	19.	24.	19.	27.	29.	23.	14.
19218	26.	22.	28.	25.	29.	24.	23.	20.	24.	23.	24.	32.	25.	23.
19219	23.	23.	32.	30.	26.	31.	29.	21.	22.	20.	23.	31.	30.	24.
19220	30.	30.	30.	21.	26.	29.	27.	3.	2.	13.	5.	13.	19.	24.

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Last value recorded before cohabitation.

b. Value not tabulated due to spillage or presumed spillage.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B29 (PAGE 1): MATERNAL WATER CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY														
STATUS	DAYS	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 7	7 - 8	8 - 9	9 - 10	10 - 11	11 - 12	12 - 13
RAT #	DOSAGE GROUP I	0 (CARRIER) MG/KG/DAY												
19101 P		31.	29.	34.	40.	34.	27.	30.	31.	33.	33.	34.	38.	32.
19102 P		27.	38.	23.	32.	40.	40.	31.	30.	28.	41.	37.	48.	43.
19103 P		40.	28.	33.	46.	45.	34.	35.	41.	43.	51.	69.	69.	74.
19104 P		22.	27.	20.	26.	37.	32.	23.	24.	29.	40.	37.	36.	41.
19105 P		32.	29.	35.	38.	33.	34.	a	46.	a	51.	67.	57.	68.
19107 P		30.	48.	29.	36.	52.	57.	57.	43.	53.	49.	79.	a	a
19108 P		26.	24.	28.	33.	30.	30.	23.	28.	36.	36.	39.	40.	43.
19109 P		19.	19.	23.	31.	28.	24.	23.	26.	26.	27.	32.	26.	25.
19110 P		24.	28.	25.	26.	35.	31.	24.	20.	25.	27.	30.	25.	30.
19111 P		35.	35.	32.	39.	65.	67.	80.	67.	a	a	72.	66.	54.
19112 P		30.	31.	26.	31.	41.	15.	27.	28.	25.	23.	19.	23.	33.
19113 P		26.	31.	19.	35.	40.	34.	32.	29.	36.	27.	37.	54.	55.
19114 P		36.	29.	37.	46.	43.	38.	27.	32.	50.	45.	55.	56.	49.
19115 P		32.	27.	32.	36.	38.	23.	29.	38.	42.	39.	42.	51.	48.
19116 P		25.	32.	25.	29.	27.	31.	24.	24.	25.	33.	39.	40.	38.
19117 P		27.	34.	36.	38.	23.	34.	32.	38.	36.	29.	34.	44.	35.
19119 P		26.	19.	25.	34.	34.	24.	23.	25.	35.	31.	36.	42.	41.
19120 NP		47.	50.	56.	47.	62.	54.	45.	67.	67.	75.	82.	a	a
19123 P		30.	34.	31.	26.	31.	45.	41.	23.	31.	35.	43.	38.	45.
19124 P		37.	40.	39.	28.	40.	53.	42.	18.	27.	43.	48.	48.	49.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Value not tabulated due to spillage or presumed spillage.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B29 (PAGE 2): MATERNAL WATER CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY								
STATUS DAYS 13 - 14 14 - 15 15 - 16 16 - 17 17 - 18 18 - 19 19 - 20 20 - 21								
RAT #	DOSAGE GROUP I				0 (CARRIER) MG/KG/DAY			
19101 P	34.	43.	43.	42.	39.	42.	33.	40.
19102 P	46.	41.	44.	44.	48.	45.	42.	39.
19103 P	50.	73.	87.	78.	63.	71.	47.	52.
19104 P	38.	32.	42.	42.	41.	36.	35.	29.
19105 P	75.	86.	a	81.	56.	58.	60.	a
19107 P	87.	a	a	64.	86.	51.	59.	53.
19108 P	39.	40.	46.	45.	43.	44.	43.	41.
19109 P	30.	31.	33.	38.	32.	34.	32.	35.
19110 P	28.	31.	35.	37.	38.	34.	36.	33.
19111 P	42.	47.	86.	62.	62.	52.	58.	43.
19112 P	31.	37.	41.	51.	45.	41.	42.	32.
19113 P	47.	44.	51.	59.	62.	56.	53.	47.
19114 P	46.	48.	51.	58.	51.	56.	47.	45.
19115 P	47.	48.	51.	49.	47.	56.	51.	49.
19116 P	33.	35.	38.	41.	37.	40.	40.	36.
19117 P	34.	34.	38.	37.	42.	39.	29.	26.
19119 P	39.	46.	47.	50.	49.	46.	46.	49.
19120 NP	71.	67.	74.	54.	44.	43.	61.	22.
19123 P	40.	39.	43.	43.	49.	44.	48.	42.
19124 P	56.	50.	51.	64.	61.	68.	56.	63.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Value not tabulated due to spillage or presumed spillage.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B29 (PAGE 3): MATERNAL WATER CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY													
STATUS DAYS	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 7	7 - 8	8 - 9	9 - 10	10 - 11	11 - 12	12 - 13
RAT #	DOSAGE GROUP II			0.01 MG/KG/DAY									
19125 P	23.	24.	33.	40.	34.	25.	26.	32.	33.	32.	47.	42.	45.
19127 NP	39.	36.	51.	61.	57.	49.	46.	48.	66.	61.	62.	58.	61.
19128 P	29.	21.	32.	38.	30.	24.	24.	31.	40.	37.	46.	40.	38.
19130 P	30.	23.	32.	30.	28.	32.	26.	30.	41.	40.	40.	40.	39.
19131 P	29.	26.	38.	51.	42.	30.	36.	25.	45.	47.	53.	55.	54.
19132 P	38.	41.	37.	41.	56.	45.	36.	30.	35.	36.	46.	45.	52.
19133 P	33.	30.	37.	25.	31.	42.	36.	30.	30.	38.	45.	55.	44.
19134 P	32.	41.	40.	27.	41.	49.	46.	37.	36.	43.	60.	54.	53.
19135 P	28.	23.	27.	30.	31.	17.	20.	25.	28.	67.	74.	66.	a
19136 P	31.	20.	29.	28.	5.	19.	43.	61.	a	a	a	a	a
19137 P	23.	30.	34.	25.	36.	46.	34.	27.	26.	29.	32.	31.	29.
19139 P	37.	50.	48.	33.	44.	58.	50.	38.	45.	43.	64.	55.	59.
19140 P	45.	41.	55.	62.	37.	41.	44.	37.	56.	42.	44.	44.	53.
19141 P	26.	32.	40.	36.	35.	43.	40.	38.	47.	40.	50.	45.	47.
19143 P	25.	36.	34.	37.	55.	59.	35.	45.	48.	63.	52.	64.	68.
19144 P	26.	31.	44.	43.	39.	33.	40.	55.	49.	49.	56.	55.	54.
19145 P	54.	19.	29.	28.	31.	24.	26.	26.	31.	33.	37.	36.	34.
19146 P	31.	39.	44.	34.	35.	41.	45.	39.	46.	54.	54.	53.	55.
19147 P	41.	24.	33.	25.	24.	39.	a	37.	b	34.	39.	40.	41.
19148 P	35.	36.	52.	53.	41.	27.	35.	37.	41.	37.	37.	35.	44.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Value not tabulated due to spillage or presumed spillage.

b. Value was not recorded.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B29 (PAGE 4): MATERNAL WATER CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY								
STATUS DAYS 13 - 14 14 - 15 15 - 16 16 - 17 17 - 18 18 - 19 19 - 20 20 - 21								
RAT #	DOSAGE GROUP II				0.01 MG/KG/DAY			
19125 P	37.	42.	40.	47.	45.	43.	45.	44.
19127 NP	57.	52.	36.	47.	43.	35.	23.	32.
19128 P	36.	42.	51.	56.	48.	54.	45.	44.
19130 P	34.	39.	38.	42.	40.	44.	39.	37.
19131 P	51.	50.	53.	66.	60.	83.	70.	58.
19132 P	50.	50.	51.	58.	64.	61.	60.	48.
19133 P	44.	43.	47.	52.	58.	47.	45.	45.
19134 P	47.	52.	59.	59.	64.	56.	a	a
19135 P	55.	65.	51.	60.	68.	56.	55.	47.
19136 P	a	66.	83.	a	a	60.	50.	59.
19137 P	27.	25.	31.	32.	35.	40.	31.	25.
19139 P	55.	59.	63.	59.	53.	77.	63.	50.
19140 P	53.	54.	64.	66.	63.	72.	69.	47.
19141 P	46.	54.	42.	48.	46.	48.	30.	54.
19143 P	a	a	a	a	a	72.	a	a
19144 P	60.	56.	53.	57.	65.	66.	52.	70.
19145 P	38.	37.	40.	45.	44.	43.	40.	36.
19146 P	58.	51.	57.	54.	45.	66.	72.	76.
19147 P	33.	41.	39.	60.	59.	67.	49.	46.
19148 P	44.	50.	57.	66.	57.	61.	50.	44.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Value not tabulated due to spillage or presumed spillage.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B29 (PAGE 5): MATERNAL WATER CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

-----														
PREGNANCY														
STATUS	DAYS	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 7	7 - 8	8 - 9	9 - 10	10 - 11	11 - 12	12 - 13
-----														
RAT #	DOSAGE	GROUP III			0.1 MG/KG/DAY									
-----														
19150 P	34.	33.	48.	51.	50.	39.	38.	41.	49.	46.	50.	46.	42.	
19151 P	26.	26.	35.	a	34.	33.	28.	32.	39.	30.	36.	52.	53.	
19152 P	46.	47.	52.	36.	48.	50.	37.	43.	43.	40.	55.	53.	64.	
19153 NP	43.	42.	40.	30.	43.	42.	50.	42.	41.	41.	54.	52.	39.	
19155 P	24.	36.	35.	35.	31.	52.	43.	24.	28.	33.	47.	41.	53.	
19156 NP	28.	28.	26.	30.	37.	34.	27.	25.	39.	41.	39.	40.	34.	
19157 P	30.	35.	38.	33.	36.	35.	36.	32.	40.	38.	46.	63.	52.	
19158 P	32.	31.	31.	24.	29.	39.	35.	24.	26.	29.	43.	47.	49.	
19159 P	29.	33.	28.	31.	36.	40.	28.	30.	69.	46.	60.	a	a	
19160 P	31.	38.	36.	27.	37.	28.	25.	26.	29.	37.	43.	37.	38.	
19161 P	43.	52.	71.	69.	49.	46.	44.	53.	50.	62.	69.	60.	58.	
19162 P	36.	43.	31.	36.	35.	40.	31.	37.	42.	44.	52.	38.	52.	
19164 P	33.	36.	46.	50.	41.	31.	35.	35.	42.	35.	36.	39.	40.	
19165 P	31.	47.	42.	28.	33.	47.	41.	27.	35.	49.	76.	83.	73.	
19166 NP	50.	49.	68.	37.	54.	63.	64.	36.	48.	a	a	a	a	
19167 P	29.	19.	25.	29.	32.	20.	22.	31.	33.	33.	37.	38.	41.	
19168 P	30.	39.	38.	30.	34.	31.	40.	30.	24.	45.	38.	41.	42.	
19170 P	26.	26.	32.	31.	42.	38.	24.	26.	38.	37.	36.	43.	46.	
19171 P	25.	30.	33.	51.	44.	35.	41.	40.	46.	39.	36.	47.	67.	
19172 P	20.	25.	29.	27.	32.	34.	34.	25.	23.	32.	34.	32.	36.	
-----														

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Value not tabulated due to spillage or presumed spillage.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B29 (PAGE 6): MATERNAL WATER CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY								
STATUS DAYS 13 - 14 14 - 15 15 - 16 16 - 17 17 - 18 18 - 19 19 - 20 20 - 21								
RAT #	DOSAGE GROUP III							
	0.1 MG/KG/DAY							
19150 P	46.	47.	59.	66.	59.	60.	56.	52.
19151 P	39.	45.	46.	47.	44.	58.	46.	59.
19152 P	67.	55.	59.	63.	64.	77.	68.	58.
19153 NP	35.	39.	39.	47.	63.	54.	52.	45.
19155 P	49.	49.	53.	59.	56.	54.	49.	45.
19156 NP	64.	86.	32.	31.	78.	41.	55.	69.
19157 P	50.	50.	64.	74.	68.	81.	54.	48.
19158 P	50.	42.	46.	53.	47.	51.	47.	36.
19159 P	a	a	71.	a	a	51.	61.	a
19160 P	41.	44.	47.	49.	52.	47.	44.	40.
19161 P	61.	69.	61.	60.	62.	46.	53.	53.
19162 P	49.	48.	51.	50.	51.	49.	52.	39.
19164 P	31.	40.	50.	44.	52.	43.	36.	37.
19165 P	72.	66.	53.	78.	68.	50.	43.	41.
19166 NP	a	57.	a	a	39.	a	a	73.
19167 P	36.	37.	49.	49.	41.	44.	38.	42.
19168 P	60.	51.	61.	69.	75.	76.	46.	42.
19170 P	49.	48.	49.	51.	53.	41.	46.	34.
19171 P	66.	55.	56.	63.	68.	73.	61.	56.
19172 P	35.	38.	32.	37.	37.	35.	34.	30.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Value not tabulated due to spillage or presumed spillage.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B29 (PAGE 7): MATERNAL WATER CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

-----													
PREGNANCY													
STATUS DAYS	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 7	7 - 8	8 - 9	9 - 10	10 - 11	11 - 12	12 - 13
-----													
RAT #	DOSAGE GROUP IV			1.0 MG/KG/DAY									
-----													
19173 P	22.	32.	48.	43.	26.	26.	34.	31.	31.	36.	42.	34.	39.
19174 P	35.	31.	40.	54.	51.	34.	38.	43.	51.	47.	51.	65.	60.
19175 P	25.	34.	24.	31.	34.	31.	23.	26.	25.	26.	37.	32.	34.
19176 P	44.	a	a	35.	84.	a	69.	58.	a	a	a	a	a
19177 P	30.	36.	23.	31.	34.	33.	31.	27.	27.	34.	31.	34.	46.
19178 P	50.	55.	58.	38.	49.	47.	42.	40.	42.	42.	54.	51.	46.
19179 P	27.	34.	39.	37.	27.	28.	25.	34.	30.	40.	41.	43.	39.
19180 P	39.	28.	41.	22.	38.	38.	42.	31.	29.	37.	38.	42.	42.
19181 P	47.	46.	47.	26.	42.	54.	50.	39.	40.	47.	62.	56.	55.
19182 P	36.	49.	53.	55.	44.	43.	52.	55.	47.	55.	63.	53.	51.
19184 P	33.	26.	32.	35.	25.	25.	26.	35.	39.	30.	33.	36.	41.
19185 P	27.	30.	38.	43.	39.	23.	31.	31.	43.	37.	48.	51.	53.
19186 P	25.	25.	22.	27.	39.	29.	22.	23.	28.	38.	37.	37.	38.
19187 P	34.	25.	34.	43.	37.	25.	32.	38.	52.	43.	38.	45.	44.
19188 P	33.	32.	33.	33.	31.	25.	24.	31.	78.	58.	81.	53.	44.
19189 P	32.	30.	31.	24.	24.	36.	30.	22.	25.	27.	32.	29.	28.
19190 P	32.	36.	35.	40.	32.	44.	30.	37.	32.	36.	33.	39.	50.
19191 P	31.	29.	26.	31.	36.	32.	20.	25.	23.	32.	31.	38.	41.
19193 P	28.	32.	26.	30.	26.	26.	26.	17.	23.	31.	33.	36.	42.
19196 P	33.	27.	33.	51.	36.	28.	29.	36.	44.	42.	41.	52.	54.
-----													

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Value not tabulated due to spillage or presumed spillage.



PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B29 (PAGE 8): MATERNAL WATER CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY								
STATUS DAYS 13 - 14 14 - 15 15 - 16 16 - 17 17 - 18 18 - 19 19 - 20 20 - 21								
RAT #	DOSAGE GROUP IV		1.0 MG/KG/DAY					
19173 P	38.	46.	42.	43.	49.	46.	47.	37.
19174 P	57.	60.	63.	60.	56.	58.	54.	42.
19175 P	36.	32.	40.	44.	42.	40.	46.	35.
19176 P	a	a	61.	84.	76.	80.	77.	77.
19177 P	36.	38.	43.	47.	48.	45.	43.	35.
19178 P	59.	56.	56.	64.	61.	62.	52.	47.
19179 P	41.	41.	43.	42.	33.	50.	41.	35.
19180 P	45.	45.	48.	50.	55.	49.	46.	35.
19181 P	65.	74.	54.	62.	60.	61.	49.	58.
19182 P	56.	a	67.	a	78.	69.	57.	49.
19184 P	41.	42.	47.	48.	48.	53.	43.	41.
19185 P	54.	51.	57.	56.	54.	55.	48.	45.
19186 P	36.	37.	44.	51.	54.	52.	51.	43.
19187 P	42.	65.	67.	65.	47.	68.	74.	56.
19188 P	53.	55.	62.	55.	46.	49.	47.	41.
19189 P	39.	29.	30.	30.	35.	37.	31.	33.
19190 P	41.	38.	47.	70.	62.	49.	58.	48.
19191 P	36.	34.	41.	47.	45.	34.	43.	33.
19193 P	41.	40.	45.	48.	61.	55.	46.	34.
19196 P	47.	44.	53.	55.	53.	50.	52.	45.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Value not tabulated due to spillage or presumed spillage.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B29 (PAGE 9): MATERNAL WATER CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

-----														
PREGNANCY														
STATUS	DAYS	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 7	7 - 8	8 - 9	9 - 10	10 - 11	11 - 12	12 - 13
-----														
RAT #	DOSAGE	30.0 MG/KG/DAY												
-----														
19197 P		21.	19.	25.	29.	33.	25.	29.	23.	a	28.	33.	37.	33.
19198 P		35.	30.	36.	33.	35.	26.	34.	26.	30.	32.	41.	37.	39.
19199 P		30.	34.	34.	40.	42.	23.	32.	b	33.	36.	42.	45.	40.
19200 P		28.	290	28.	37.	37.	28.	26.	28.	28.	35.	32.	38.	45.
19201 P		22.	38.	37.	14.	22.	31.	33.	41.	45.	69.	a	a	a
19202 P		32.	29.	33.	19.	30.	38.	33.	33.	28.	35.	42.	39.	46.
19204 P		34.	29.	38.	46.	47.	35.	32.	43.	46.	53.	61.	54.	46.
19205 P		22.	28.	49.	51.	58.	39.	42.	41.	47.	46.	45.	34.	38.
19206 P		26.	24.	33.	39.	32.	26.	28.	37.	39.	40.	41.	45.	44.
19207 P		26.	32.	39.	47.	7.	22.	36.	43.	44.	41.	35.	51.	43.
19208 P		39.	54.	41.	47.	39.	19.	26.	29.	42.	36.	29.	34.	53.
19210 P		32.	32.	34.	17.	42.	49.	41.	23.	27.	34.	37.	34.	37.
19211 P		22.	36.	35.	30.	32.	41.	37.	24.	32.	23.	40.	34.	40.
19212 P		37.	37.	29.	38.	40.	37.	26.	30.	38.	46.	40.	42.	49.
19213 P		33.	33.	28.	43.	41.	46.	32.	31.	32.	47.	46.	38.	41.
19215 P		36.	65.	a	26.	a	70.	a	77.	35.	83.	a	a	a
19216 P		38.	39.	31.	33.	34.	42.	43.	27.	31.	32.	45.	42.	39.
19218 P		31.	38.	37.	32.	42.	49.	39.	29.	29.	39.	45.	46.	48.
19219 P		31.	30.	28.	30.	25.	33.	26.	26.	31.	31.	26.	29.	35.
19220 P		30.	27.	27.	28.	34.	16.	21.	23.	27.	35.	33.	39.	37.
-----														

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Value not tabulated due to spillage or presumed spillage.

b. Value was not recorded.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B29 (PAGE 10): MATERNAL WATER CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY								
STATUS DAYS 13 - 14 14 - 15 15 - 16 16 - 17 17 - 18 18 - 19 19 - 20 20 - 21								
RAT #	DOSAGE GROUP V		30.0 MG/KG/DAY					
19197 P	30.	36.	37.	46.	45.	37.	36.	35.
19198 P	45.	38.	41.	46.	51.	51.	44.	42.
19199 P	40.	36.	48.	53.	47.	44.	37.	16.
19200 P	43.	41.	36.	53.	43.	48.	47.	42.
19201 P	a	a	a	a	a	a	62.	37.
19202 P	46.	51.	36.	54.	45.	52.	41.	43.
19204 P	45.	52.	81.	a	a	a	58.	55.
19205 P	52.	51.	63.	a	63.	71.	61.	48.
19206 P	48.	39.	44.	50.	45.	47.	46.	36.
19207 P	47.	43.	51.	62.	46.	51.	48.	45.
19208 P	50.	54.	65.	69.	77.	75.	80.	54.
19210 P	37.	37.	39.	45.	51.	56.	45.	30.
19211 P	34.	35.	30.	40.	53.	38.	43.	41.
19212 P	44.	46.	48.	61.	56.	62.	56.	50.
19213 P	44.	39.	48.	53.	52.	49.	50.	47.
19215 P	a	a	a	a	63.	a	61.	a
19216 P	43.	42.	42.	47.	58.	56.	50.	40.
19218 P	53.	51.	65.	66.	67.	62.	50.	47.
19219 P	32.	39.	39.	40.	48.	44.	39.	35.
19220 P	38.	34.	41.	46.	46.	47.	43.	40.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Value not tabulated due to spillage or presumed spillage.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B30 (PAGE 1): FEED CONSUMPTION VALUES - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAYS	1- 2	2- 3	3- 4	4- 5	5- 6	6- 7	7- 8	8- 9	9- 10	10- 11	11- 12	12- 13	13- 14	14- 15a
RAT #	DOSAGE GROUP I				0 (CARRIER) MG/KG/DAY									
19101	15.	22.	19.	18.	15.	19.	22.	20.	15.	23.	17.	18.	17.	17.
19102	21.	23.	19.	15.	20.	22.	19.	17.	21.	24.	19.	17.	19.	23.
19103	16.	17.	17.	19.	17.	19.	19.	20.	15.	15.	12.	21.	15.	21.
19104	17.	16.	15.	12.	17.	17.	19.	13.	18.	20.	17.	13.	13.	17.
19105	19.	20.	23.	23.	18.	21.	21.	22.	16.	20.	20.	23.	15.	21.
19106	21.	20.	22.	21.	19.	22.	22.	19.	18.	24.	21.	21.	18.	22.
19107	15.	18.	18.	19.	14.	19.	21.	20.	15.	22.	16.	16.	12.	15.
19108	15.	17.	19.	16.	13.	17.	19.	16.	12.	17.	14.	17.	10.	17.
19109	13.	17.	19.	18.	14.	16.	18.	17.	13.	18.	16.	16.	13.	18.
19110	19.	20.	18.	16.	b	19.	21.	16.	17.	23.	15.	16.	19.	22.
19111	20.	19.	14.	18.	23.	21.	19.	35.	22.	23.	16.	20.	19.	b
19112	17.	17.	19.	18.	18.	17.	21.	20.	21.	56.	39.	22.	20.	21.
19113	20.	20.	22.	18.	21.	19.	24.	16.	19.	22.	18.	19.	21.	19.
19114	18.	19.	20.	20.	18.	21.	18.	17.	16.	20.	17.	22.	18.	16.
19115	17.	19.	20.	18.	17.	20.	21.	21.	19.	23.	19.	21.	19.	18.
19116	18.	18.	16.	15.	18.	17.	18.	16.	17.	20.	15.	16.	18.	20.
19117	16.	19.	21.	21.	18.	16.	23.	22.	21.	20.	19.	c	25.	12.
19118	21.	16.	20.	19.	21.	17.	22.	20.	21.	17.	16.	18.	21.	13.
19119	16.	19.	21.	18.	17.	21.	24.	19.	14.	20.	17.	20.	18.	14.
19120	20.	18.	12.	19.	20.	19.	14.	21.	17.	21.	12.	20.	21.	15.
19121	21.	11.	20.	20.	22.	17.	21.	20.	18.	16.	18.	14.	15.	18.
19122	20.	22.	20.	17.	20.	22.	21.	17.	12.	23.	17.	20.	21.	18.
19123	19.	19.	17.	22.	21.	19.	23.	20.	19.	21.	11.	20.	24.	17.
19124	21.	20.	16.	21.	21.	20.	17.	18.	18.	19.	16.	21.	21.	16.

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

- a. Last value recorded before cohabitation.
- b. Spilled feed precluded the calculation of this value.
- c. Value was incorrectly recorded.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B30 (PAGE 2): FEED CONSUMPTION VALUES - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAYS	1- 2	2- 3	3- 4	4- 5	5- 6	6- 7	7- 8	8- 9	9- 10	10- 11	11- 12	12- 13	13- 14	14- 15a
RAT #	DOSAGE GROUP II 0.01 MG/KG/DAY													
19125	19.	18.	19.	16.	18.	23.	21.	19.	16.	20.	22.	21.	17.	17.
19126	16.	14.	20.	18.	18.	14.	19.	17.	17.	17.	16.	22.	19.	13.
19127	14.	18.	20.	20.	12.	18.	19.	21.	17.	21.	17.	21.	18.	15.
19128	18.	21.	20.	19.	17.	19.	21.	19.	18.	20.	19.	21.	17.	18.
19129	16.	17.	18.	18.	14.	19.	19.	19.	14.	20.	17.	19.	14.	15.
19130	15.	17.	21.	17.	16.	17.	35.	18.	15.	21.	18.	20.	17.	18.
19131	18.	18.	17.	17.	14.	19.	17.	17.	13.	19.	16.	17.	14.	16.
19132	18.	20.	14.	12.	27.	17.	18.	13.	16.	20.	18.	11.	20.	14.
19133	18.	13.	19.	16.	18.	15.	17.	18.	18.	15.	16.	20.	21.	13.
19134	19.	14.	17.	20.	19.	16.	19.	20.	19.	15.	16.	23.	19.	13.
19135	17.	17.	19.	19.	21.	16.	15.	21.	19.	21.	16.	17.	21.	16.
19136	17.	22.	20.	21.	14.	21.	22.	22.	16.	23.	20.	24.	17.	16.
19137	13.	15.	17.	17.	14.	16.	18.	17.	14.	21.	15.	19.	20.	13.
19138	18.	20.	19.	18.	17.	19.	20.	19.	18.	19.	17.	22.	20.	15.
19139	17.	14.	16.	18.	18.	14.	18.	18.	19.	18.	13.	19.	23.	17.
19140	20.	24.	18.	20.	15.	20.	20.	16.	15.	22.	17.	20.	17.	19.
19141	21.	16.	15.	15.	17.	16.	10.	19.	14.	19.	14.	19.	17.	13.
19142	18.	21.	20.	21.	19.	23.	24.	22.	20.	23.	21.	29.	20.	22.
19143	19.	23.	24.	21.	21.	24.	26.	19.	20.	25.	18.	27.	21.	16.
19144	21.	21.	21.	21.	20.	15.	21.	18.	12.	14.	19.	19.	18.	12.
19145	14.	16.	18.	19.	13.	18.	17.	16.	11.	17.	17.	15.	13.	16.
19146	18.	18.	18.	17.	16.	16.	18.	17.	16.	9.	14.	17.	17.	9.
19147	19.	17.	13.	17.	18.	16.	14.	18.	16.	15.	13.	18.	19.	12.
19148	16.	18.	20.	17.	17.	19.	22.	22.	18.	21.	18.	24.	17.	18.

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Last value recorded before cohabitation.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B30 (PAGE 3): FEED CONSUMPTION VALUES - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAYS	1- 2	2- 3	3- 4	4- 5	5- 6	6- 7	7- 8	8- 9	9- 10	10- 11	11- 12	12- 13	13- 14	14- 15a
RAT #	DOSAGE GROUP III				0.1 MG/KG/DAY									
19149	22.	17.	19.	21.	20.	15.	19.	22.	17.	17.	18.	23.	20.	12.
19150	17.	20.	20.	20.	15.	20.	21.	19.	15.	21.	17.	19.	17.	16.
19151	20.	15.	18.	19.	19.	19.	15.	18.	17.	21.	16.	16.	20.	16.
19152	21.	15.	21.	21.	21.	17.	23.	22.	18.	19.	16.	24.	17.	13.
19153	15.	20.	21.	20.	16.	20.	23.	22.	18.	23.	20.	24.	20.	16.
19154	17.	13.	19.	19.	19.	15.	22.	22.	18.	17.	21.	24.	18.	11.
19155	17.	13.	16.	18.	15.	13.	19.	18.	14.	16.	15.	16.	17.	10.
19156	20.	17.	17.	12.	20.	17.	17.	14.	16.	17.	16.	12.	19.	13.
19157	18.	16.	17.	18.	18.	12.	14.	19.	18.	19.	15.	14.	17.	18.
19158	20.	17.	18.	14.	17.	20.	18.	19.	14.	17.	18.	20.	19.	15.
19159	18.	13.	19.	17.	20.	14.	18.	17.	17.	10.	15.	20.	21.	15.
19160	17.	14.	16.	18.	19.	14.	17.	16.	16.	13.	15.	21.	19.	11.
19161	20.	19.	21.	21.	17.	20.	20.	17.	17.	18.	16.	21.	17.	16.
19162	20.	21.	21.	16.	20.	21.	20.	18.	19.	23.	16.	18.	22.	19.
19163	17.	14.	18.	19.	18.	14.	19.	19.	18.	16.	14.	22.	19.	13.
19164	23.	26.	21.	16.	15.	18.	19.	16.	10.	18.	14.	18.	14.	17.
19165	20.	14.	22.	20.	21.	17.	21.	21.	16.	18.	17.	22.	20.	11.
19166	19.	15.	21.	21.	22.	16.	22.	22.	20.	18.	41.	27.	21.	14.
19167	18.	14.	16.	21.	20.	16.	16.	18.	12.	14.	14.	21.	18.	14.
19168	18.	15.	18.	18.	19.	11.	21.	16.	16.	15.	14.	19.	18.	11.
19169	17.	18.	18.	17.	17.	18.	21.	15.	17.	19.	15.	19.	18.	15.
19170	17.	18.	17.	16.	17.	19.	20.	16.	16.	19.	17.	16.	17.	17.
19171	18.	16.	16.	13.	17.	17.	18.	18.	15.	17.	15.	18.	17.	15.
19172	18.	12.	17.	18.	17.	13.	17.	18.	15.	11.	14.	20.	15.	8.

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Last value recorded before cohabitation.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B30 (PAGE 4): FEED CONSUMPTION VALUES - PRECOHABITATION - INDIVIDUAL DATA - PART D

DAYS	1- 2	2- 3	3- 4	4- 5	5- 6	6- 7	7- 8	8- 9	9- 10	10- 11	11- 12	12- 13	13- 14	14- 15a
RAT #	DOSAGE GROUP IV 1.0 MG/KG/DAY													
19173	17.	14.	15.	18.	15.	15.	17.	17.	15.	15.	16.	20.	18.	13.
19174	16.	19.	22.	19.	14.	18.	19.	17.	14.	20.	19.	21.	16.	16.
19175	15.	16.	14.	11.	15.	16.	15.	13.	15.	17.	12.	13.	19.	15.
19176	18.	20.	20.	18.	16.	18.	22.	19.	16.	22.	22.	22.	18.	13.
19177	17.	18.	17.	12.	18.	15.	29.	14.	15.	20.	14.	15.	19.	16.
19178	19.	16.	15.	18.	19.	19.	19.	20.	18.	21.	18.	22.	29.	17.
19179	17.	19.	14.	21.	21.	20.	17.	16.	20.	21.	19.	20.	16.	17.
19180	21.	17.	15.	19.	21.	16.	16.	22.	20.	18.	16.	23.	22.	14.
19181	18.	19.	13.	19.	19.	18.	14.	23.	19.	17.	15.	18.	20.	16.
19182	18.	14.	17.	18.	18.	13.	18.	17.	17.	15.	14.	23.	17.	11.
19183	21.	16.	19.	20.	20.	16.	20.	23.	19.	16.	16.	21.	20.	14.
19184	17.	22.	18.	23.	19.	20.	23.	20.	19.	23.	18.	24.	18.	21.
19185	15.	17.	18.	16.	15.	16.	19.	17.	11.	19.	15.	17.	17.	15.
19186	19.	18.	18.	16.	21.	16.	19.	14.	18.	17.	16.	16.	20.	14.
19187	15.	17.	18.	16.	16.	16.	21.	17.	13.	20.	17.	21.	14.	15.
19188	19.	19.	19.	17.	14.	17.	21.	16.	12.	15.	16.	17.	12.	14.
19189	17.	18.	18.	17.	18.	18.	20.	18.	15.	20.	15.	21.	20.	15.
19190	25.	24.	20.	12.	23.	20.	20.	18.	22.	22.	18.	12.	23.	17.
19191	20.	21.	17.	16.	21.	19.	18.	17.	18.	19.	14.	16.	24.	14.
19192	b	16.	18.	18.	20.	15.	13.	19.	18.	20.	15.	15.	16.	18.
19193	17.	24.	18.	15.	17.	17.	20.	18.	9.	15.	14.	18.	17.	10.
19194	20.	14.	21.	19.	19.	14.	21.	21.	18.	18.	12.	20.	20.	17.
19195	18.	18.	19.	19.	21.	12.	23.	18.	17.	17.	16.	24.	17.	8.
19196	23.	20.	22.	18.	17.	17.	19.	19.	14.	17.	13.	17.	14.	15.

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Last value recorded before cohabitation.

b. Spilled feed precluded the calculation of this value.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B30 (PAGE 5): FEED CONSUMPTION VALUES - PRECOHABITATION - INDIVIDUAL DATA - PART D

RAT #	DAYS															14- 15a
	DOSAGE GROUP V															
	30.0 MG/KG/DAY															
1-	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
19197	14.	22.	16.	19.	12.	20.	21.	18.	12.	17.	14.	18.	12.	19.	19.	
19198	20.	13.	18.	19.	20.	13.	19.	20.	20.	18.	14.	26.	19.	15.	15.	
19199	18.	18.	24.	22.	16.	20.	25.	22.	14.	22.	18.	21.	16.	19.	15.	
19200	18.	19.	20.	15.	22.	19.	20.	20.	19.	21.	17.	20.	21.	17.	17.	
19201	20.	14.	20.	20.	20.	16.	22.	23.	20.	18.	18.	22.	21.	17.	17.	
19202	19.	19.	19.	20.	19.	37.	21.	23.	22.	21.	17.	24.	23.	17.	17.	
19203	16.	20.	18.	20.	14.	19.	20.	17.	15.	22.	15.	21.	16.	16.	16.	
19204	19.	20.	18.	19.	20.	21.	21.	19.	19.	21.	19.	22.	21.	19.	19.	
19205	17.	21.	20.	20.	16.	22.	23.	17.	16.	20.	15.	20.	21.	18.	18.	
19206	18.	23.	25.	25.	22.	24.	24.	19.	17.	20.	20.	21.	18.	20.	20.	
19207	15.	18.	17.	19.	14.	17.	22.	16.	12.	18.	16.	19.	14.	14.	14.	
19208	17.	20.	17.	16.	20.	19.	21.	17.	19.	22.	16.	20.	18.	17.	17.	
19209	17.	19.	11.	16.	16.	13.	18.	17.	15.	15.	14.	19.	19.	13.	13.	
19210	18.	18.	18.	17.	20.	16.	18.	19.	17.	16.	15.	22.	17.	9.	9.	
19211	19.	18.	16.	17.	21.	18.	18.	20.	17.	16.	15.	18.	20.	16.	16.	
19212	18.	18.	16.	15.	21.	18.	20.	13.	18.	20.	16.	15.	20.	20.	20.	
19213	22.	22.	20.	15.	24.	21.	22.	18.	20.	23.	15.	13.	20.	18.	18.	
19214	20.	19.	15.	19.	23.	19.	23.	14.	21.	25.	16.	23.	17.	20.	20.	
19215	17.	17.	20.	21.	19.	14.	20.	19.	20.	17.	17.	24.	21.	9.	9.	
19216	19.	18.	15.	18.	19.	20.	17.	19.	19.	19.	16.	18.	20.	19.	19.	
19217	18.	12.	19.	17.	18.	18.	23.	20.	18.	14.	16.	19.	16.	6.	6.	
19218	b	c	15.	17.	17.	15.	15.	19.	15.	16.	11.	17.	17.	14.	14.	
19219	17.	19.	20.	19.	19.	b	22.	18.	19.	19.	14.	23.	24.	17.	17.	
19220	23.	21.	19.	19.	22.	22.	20.	16.	19.	22.	15.	19.	20.	18.	18.	

DAY = DAY OF STUDY

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

- a. Last value recorded before cohabitation.
- b. Spilled feed precluded the calculation of this value.
- c. Value was not recorded.



PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B31 (PAGE 1): MATERNAL FEED CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

-----														
PREGNANCY														
STATUS	DAYS	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 7	7 - 8	8 - 9	9 - 10	10 - 11	11 - 12	12 - 13
-----														
RAT #	DOSAGE GROUP I	0 (CARRIER) MG/KG/DAY												
-----														
19101 P	26.	22.	25.	29.	27.	20.	31.	22.	27.	25.	24.	27.	19.	
19102 P	22.	28.	17.	25.	31.	32.	19.	34.	20.	27.	25.	29.	23.	
19103 P	25.	17.	22.	18.	29.	15.	28.	19.	21.	21.	23.	21.	20.	
19104 P	19.	20.	15.	20.	23.	24.	10.	28.	19.	24.	24.	28.	24.	
19105 P	21.	19.	27.	30.	30.	19.	31.	a	30.	26.	29.	29.	25.	
19107 P	19.	22.	19.	22.	25.	25.	15.	30.	22.	22.	23.	23.	31.	
19108 P	20.	20.	20.	21.	25.	13.	26.	16.	23.	23.	25.	24.	21.	
19109 P	21.	16.	19.	25.	24.	17.	26.	21.	25.	21.	24.	26.	21.	
19110 P	20.	22.	19.	22.	26.	28.	14.	28.	17.	23.	20.	23.	19.	
19111 P	23.	16.	17.	26.	30.	32.	15.	33.	20.	29.	22.	27.	24.	
19112 P	24.	21.	22.	34.	42.	29.	17.	31.	19.	29.	25.	24.	30.	
19113 P	20.	22.	18.	24.	23.	25.	18.	28.	18.	24.	20.	26.	30.	
19114 P	24.	17.	22.	27.	24.	15.	25.	18.	28.	22.	27.	28.	22.	
19115 P	23.	17.	22.	25.	27.	13.	25.	22.	23.	25.	29.	29.	24.	
19116 P	19.	20.	17.	22.	41.	25.	14.	30.	21.	26.	26.	25.	34.	
19117 P	23.	26.	29.	29.	17.	32.	23.	51.	20.	25.	28.	25.	25.	
19119 P	22.	15.	21.	24.	30.	13.	31.	19.	27.	23.	26.	27.	26.	
19120 NP	19.	22.	17.	23.	26.	30.	16.	31.	21.	26.	24.	27.	29.	
19123 P	24.	24.	21.	18.	22.	27.	29.	12.	30.	20.	25.	23.	26.	
19124 P	18.	25.	25.	18.	26.	28.	29.	16.	26.	19.	29.	24.	28.	
-----														

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Value was not recorded.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B31 (PAGE 2): MATERNAL FEED CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY								
STATUS DAYS 13 - 14 14 - 15 15 - 16 16 - 17 17 - 18 18 - 19 19 - 20 20 - 21								
RAT #	DOSAGE GROUP I				0 (CARRIER) MG/KG/DAY			
19101 P	21.	25.	33.	24.	27.	24.	26.	23.
19102 P	26.	23.	26.	30.	28.	29.	25.	26.
19103 P	12.	21.	28.	22.	27.	26.	25.	24.
19104 P	19.	21.	23.	29.	22.	23.	22.	22.
19105 P	26.	26.	31.	26.	31.	25.	28.	26.
19107 P	24.	25.	26.	33.	25.	29.	24.	24.
19108 P	22.	20.	26.	25.	25.	23.	26.	20.
19109 P	22.	24.	27.	23.	25.	22.	26.	22.
19110 P	20.	20.	20.	25.	24.	25.	20.	23.
19111 P	20.	20.	25.	32.	22.	26.	22.	28.
19112 P	20.	28.	26.	37.	22.	31.	29.	26.
19113 P	26.	26.	30.	27.	25.	33.	29.	25.
19114 P	25.	22.	29.	28.	27.	26.	24.	26.
19115 P	23.	26.	27.	28.	31.	28.	28.	23.
19116 P	19.	24.	25.	27.	22.	27.	25.	22.
19117 P	24.	26.	22.	23.	25.	25.	24.	19.
19119 P	26.	28.	29.	27.	32.	28.	29.	26.
19120 NP	27.	25.	20.	16.	19.	20.	18.	11.
19123 P	23.	21.	27.	24.	30.	28.	25.	28.
19124 P	31.	27.	22.	30.	24.	31.	25.	25.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)  
DAYS = DAYS OF PRESUMED GESTATION  
ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B31 (PAGE 3): MATERNAL FEED CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

-----													
PREGNANCY													
STATUS DAYS	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 7	7 - 8	8 - 9	9 - 10	10 - 11	11 - 12	12 - 13
-----													
RAT #	DOSAGE GROUP II			0.01 MG/KG/DAY									
-----													
19125 P	20.	17.	22.	18.	27.	12.	24.	16.	23.	21.	29.	26.	20.
19127 NP	22.	19.	26.	29.	32.	23.	34.	24.	32.	27.	29.	31.	27.
19128 P	19.	12.	22.	22.	24.	12.	28.	21.	29.	27.	30.	28.	23.
19130 P	23.	18.	23.	26.	27.	19.	34.	20.	29.	26.	23.	25.	23.
19131 P	20.	16.	19.	23.	25.	13.	25.	13.	23.	23.	26.	27.	25.
19132 P	19.	20.	14.	20.	25.	26.	14.	27.	18.	24.	20.	24.	26.
19133 P	21.	21.	22.	15.	23.	27.	30.	16.	28.	22.	28.	23.	28.
19134 P	19.	22.	16.	18.	21.	28.	25.	16.	26.	18.	20.	25.	23.
19135 P	24.	18.	20.	22.	25.	26.	18.	22.	22.	25.	26.	25.	27.
19136 P	22.	15.	22.	29.	29.	17.	29.	22.	27.	23.	28.	24.	22.
19137 P	18.	21.	25.	16.	25.	27.	29.	16.	30.	20.	26.	22.	22.
19139 P	21.	26.	21.	15.	22.	29.	27.	16.	28.	19.	25.	23.	23.
19140 P	25.	19.	27.	26.	28.	15.	32.	15.	27.	24.	31.	22.	27.
19141 P	31.	15.	24.	19.	23.	25.	18.	24.	25.	23.	25.	23.	25.
19143 P	16.	23.	17.	24.	31.	36.	15.	33.	27.	27.	25.	31.	32.
19144 P	19.	20.	25.	22.	14.	25.	19.	26.	27.	28.	27.	26.	27.
19145 P	19.	16.	17.	17.	18.	16.	20.	17.	19.	21.	22.	23.	22.
19146 P	18.	16.	22.	17.	20.	18.	20.	23.	21.	28.	23.	24.	26.
19147 P	22.	21.	19.	16.	18.	22.	22.	16.	23.	18.	17.	19.	25.
19148 P	21.	24.	25.	27.	27.	14.	27.	18.	21.	19.	19.	22.	18.
-----													
P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)													
DAYS = DAYS OF PRESUMED GESTATION													
ALL WEIGHTS WERE RECORDED IN GRAMS (G).													

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B31 (PAGE 4): MATERNAL FEED CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY								
STATUS DAYS 13 - 14 14 - 15 15 - 16 16 - 17 17 - 18 18 - 19 19 - 20 20 - 21								
RAT #	DOSAGE GROUP II		0.01 MG/KG/DAY					
19125 P	20.	25.	27.	22.	29.	23.	22.	27.
19127 NP	22.	25.	19.	21.	27.	19.	15.	18.
19128 P	27.	24.	31.	28.	28.	28.	26.	27.
19130 P	25.	24.	27.	24.	27.	24.	25.	24.
19131 P	26.	23.	23.	26.	27.	25.	32.	24.
19132 P	19.	24.	21.	30.	22.	27.	24.	27.
19133 P	24.	24.	24.	28.	25.	28.	29.	21.
19134 P	22.	24.	28.	24.	29.	30.	26.	25.
19135 P	25.	24.	22.	26.	26.	28.	25.	23.
19136 P	22.	21.	23.	24.	24.	23.	24.	21.
19137 P	21.	18.	22.	22.	27.	23.	23.	18.
19139 P	19.	19.	20.	21.	22.	27.	25.	22.
19140 P	26.	32.	32.	36.	29.	28.	34.	26.
19141 P	25.	23.	22.	29.	25.	30.	16.	27.
19143 P	31.	27.	29.	34.	32.	30.	29.	29.
19144 P	28.	25.	27.	29.	29.	31.	18.	25.
19145 P	22.	22.	18.	24.	26.	24.	24.	19.
19146 P	23.	21.	25.	21.	17.	26.	24.	27.
19147 P	15.	18.	21.	22.	29.	23.	23.	24.
19148 P	22.	23.	24.	25.	25.	25.	30.	18.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B31 (PAGE 5): MATERNAL FEED CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY														
STATUS	DAYS	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 7	7 - 8	8 - 9	9 - 10	10 - 11	11 - 12	12 - 13
RAT #	DOSAGE GROUP	0.1 MG/KG/DAY												
19150 P		22.	19.	24.	23.	26.	14.	28.	20.	25.	28.	28.	24.	21.
19151 P		21.	18.	19.	26.	24.	16.	26.	a	23.	21.	31.	20.	21.
19152 P		20.	21.	26.	19.	22.	29.	32.	17.	33.	21.	26.	25.	30.
19153 NP		30.	24.	22.	19.	31.	29.	34.	14.	35.	22.	30.	24.	23.
19155 P		15.	24.	21.	22.	22.	30.	31.	14.	26.	19.	24.	25.	31.
19156 NP		20.	18.	19.	19.	25.	23.	14.	25.	20.	24.	23.	24.	19.
19157 P		21.	23.	22.	24.	22.	16.	27.	17.	22.	22.	27.	26.	24.
19158 P		23.	22.	25.	16.	22.	27.	26.	16.	28.	20.	26.	27.	29.
19159 P		20.	21.	15.	20.	24.	24.	13.	26.	18.	23.	21.	24.	25.
19160 P		18.	22.	19.	17.	23.	24.	28.	16.	26.	16.	23.	22.	25.
19161 P		14.	26.	22.	27.	18.	31.	19.	28.	25.	28.	24.	21.	25.
19162 P		24.	23.	19.	22.	27.	29.	20.	32.	22.	24.	25.	23.	28.
19164 P		17.	19.	24.	23.	25.	17.	26.	18.	31.	18.	31.	17.	23.
19165 P		20.	25.	21.	15.	16.	26.	28.	8.	27.	15.	28.	23.	28.
19166 NP		26.	27.	31.	25.	31.	34.	38.	15.	35.	24.	30.	28.	26.
19167 P		19.	16.	20.	20.	29.	12.	24.	20.	23.	28.	28.	26.	27.
19168 P		21.	22.	23.	17.	22.	23.	25.	13.	26.	21.	24.	23.	26.
19170 P		22.	20.	18.	21.	27.	28.	12.	27.	20.	22.	22.	21.	25.
19171 P		20.	18.	22.	25.	26.	17.	28.	17.	26.	21.	26.	22.	22.
19172 P		12.	17.	19.	17.	20.	23.	26.	14.	24.	18.	24.	29.	22.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Value was not recorded.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B31 (PAGE 6): MATERNAL FEED CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY								
STATUS DAYS 13 - 14 14 - 15 15 - 16 16 - 17 17 - 18 18 - 19 19 - 20 20 - 21								
RAT #	DOSAGE GROUP III			0.1 MG/KG/DAY				
19150 P	23.	21.	23.	25.	28.	24.	28.	28.
19151 P	24.	23.	27.	20.	26.	23.	26.	21.
19152 P	23.	23.	27.	30.	27.	28.	25.	25.
19153 NP	16.	20.	27.	23.	31.	25.	29.	25.
19155 P	25.	25.	25.	24.	27.	28.	26.	28.
19156 NP	18.	16.	17.	18.	14.	15.	16.	20.
19157 P	21.	22.	24.	22.	28.	27.	28.	23.
19158 P	28.	28.	29.	32.	31.	29.	26.	25.
19159 P	24.	24.	25.	25.	28.	26.	22.	23.
19160 P	20.	22.	23.	25.	23.	23.	24.	25.
19161 P	23.	27.	18.	26.	21.	26.	21.	20.
19162 P	23.	26.	27.	27.	24.	24.	26.	21.
19164 P	22.	23.	31.	23.	27.	28.	27.	24.
19165 P	23.	22.	26.	31.	28.	22.	25.	21.
19166 NP	18.	19.	23.	14.	17.	18.	22.	20.
19167 P	24.	24.	25.	24.	30.	27.	26.	27.
19168 P	22.	22.	22.	27.	28.	25.	27.	22.
19170 P	21.	22.	24.	28.	23.	25.	25.	17.
19171 P	23.	24.	30.	23.	27.	25.	25.	23.
19172 P	20.	20.	21.	23.	25.	21.	21.	20.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)  
 DAYS = DAYS OF PRESUMED GESTATION  
 ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B31 (PAGE 7): MATERNAL FEED CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

-----													
PREGNANCY													
STATUS DAYS	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 7	7 - 8	8 - 9	9 - 10	10 - 11	11 - 12	12 - 13
-----													
RAT #	DOSAGE GROUP IV			1.0 MG/KG/DAY									
-----													
19173 P	14.	19.	24.	26.	14.	26.	17.	22.	20.	25.	21.	21.	22.
19174 P	22.	20.	18.	23.	23.	16.	24.	17.	23.	25.	26.	25.	28.
19175 P	22.	24.	15.	22.	28.	25.	13.	28.	17.	21.	21.	25.	20.
19176 P	25.	27.	23.	17.	27.	25.	15.	9.	26.	13.	26.	20.	28.
19177 P	24.	22.	18.	20.	27.	30.	14.	28.	16.	25.	18.	24.	25.
19178 P	25.	25.	24.	21.	23.	30.	29.	12.	33.	17.	29.	25.	30.
19179 P	20.	25.	28.	26.	14.	27.	16.	26.	23.	28.	24.	27.	26.
19180 P	25.	16.	27.	17.	25.	28.	30.	12.	25.	15.	22.	23.	30.
19181 P	27.	23.	19.	15.	24.	25.	30.	16.	28.	20.	28.	28.	27.
19182 P	14.	19.	26.	28.	15.	28.	21.	28.	23.	29.	24.	23.	25.
19184 P	23.	20.	24.	28.	28.	17.	29.	23.	31.	21.	26.	25.	26.
19185 P	20.	20.	19.	30.	24.	13.	23.	18.	25.	30.	29.	22.	19.
19186 P	19.	22.	15.	21.	23.	28.	16.	27.	20.	29.	26.	27.	26.
19187 P	22.	17.	24.	24.	27.	14.	28.	20.	27.	24.	26.	22.	23.
19188 P	20.	18.	17.	20.	21.	14.	24.	21.	26.	22.	23.	21.	23.
19189 P	21.	25.	23.	20.	22.	28.	25.	16.	31.	15.	29.	18.	29.
19190 P	28.	29.	27.	29.	30.	31.	23.	34.	24.	28.	25.	31.	32.
19191 P	22.	50.	20.	22.	25.	26.	14.	29.	16.	20.	17.	28.	29.
19193 P	18.	22.	21.	17.	19.	22.	22.	13.	22.	16.	22.	21.	26.
19196 P	20.	13.	21.	24.	28.	12.	27.	20.	27.	24.	29.	26.	22.
-----													

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B31 (PAGE 8): MATERNAL FEED CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY								
STATUS DAYS 13 - 14 14 - 15 15 - 16 16 - 17 17 - 18 18 - 19 19 - 20 20 - 21								
RAT #	DOSAGE GROUP IV				1.0 MG/KG/DAY			
19173 P	29.	24.	23.	26.	23.	25.	23.	24.
19174 P	23.	23.	30.	27.	29.	25.	30.	22.
19175 P	22.	30.	24.	26.	24.	25.	23.	18.
19176 P	23.	24.	20.	32.	25.	27.	25.	21.
19177 P	22.	22.	25.	a	26.	29.	20.	29.
19178 P	23.	26.	29.	33.	30.	26.	30.	24.
19179 P	25.	26.	25.	22.	22.	30.	25.	27.
19180 P	28.	22.	26.	29.	31.	24.	26.	19.
19181 P	25.	27.	29.	34.	33.	26.	26.	23.
19182 P	23.	29.	19.	27.	23.	28.	23.	24.
19184 P	28.	27.	32.	27.	32.	32.	34.	23.
19185 P	22.	19.	25.	28.	23.	29.	29.	24.
19186 P	22.	23.	23.	26.	21.	29.	28.	27.
19187 P	23.	21.	28.	22.	27.	24.	25.	26.
19188 P	22.	23.	24.	24.	24.	25.	24.	27.
19189 P	24.	18.	21.	23.	30.	21.	25.	21.
19190 P	23.	26.	30.	42.	22.	34.	26.	31.
19191 P	21.	23.	26.	27.	26.	21.	22.	17.
19193 P	20.	18.	22.	25.	26.	20.	23.	22.
19196 P	26.	20.	28.	24.	26.	26.	27.	24.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

a. Spilled feed precluded the calculation of this value.



PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B31 (PAGE 9): MATERNAL FEED CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

-----														
PREGNANCY														
STATUS	DAYS	0 - 1	1 - 2	2 - 3	3 - 4	4 - 5	5 - 6	6 - 7	7 - 8	8 - 9	9 - 10	10 - 11	11 - 12	12 - 13
-----														
RAT #	DOSAGE	GROUP V			30.0 MG/KG/DAY									
-----														
19197 P	17.	16.	17.	24.	24.	14.	27.	17.	24.	20.	26.	26.	25.	
19198 P	23.	18.	23.	17.	22.	19.	20.	12.	28.	18.	25.	21.	23.	
19199 P	23.	23.	22.	22.	17.	12.	24.	19.	24.	22.	26.	27.	23.	
19200 P	21.	19.	25.	23.	28.	28.	15.	31.	21.	30.	24.	31.	27.	
19201 P	21.	21.	28.	27.	12.	28.	19.	22.	24.	27.	25.	23.	23.	
19202 P	24.	21.	25.	17.	24.	31.	27.	19.	34.	20.	28.	30.	30.	
19204 P	26.	22.	23.	28.	35.	14.	35.	20.	30.	27.	30.	29.	27.	
19205 P	25.	17.	22.	26.	32.	15.	33.	18.	28.	21.	28.	18.	19.	
19206 P	18.	17.	24.	20.	29.	15.	29.	28.	34.	26.	31.	29.	22.	
19207 P	20.	18.	25.	27.	27.	14.	30.	19.	30.	18.	27.	21.	19.	
19208 P	22.	27.	21.	25.	32.	31.	17.	33.	22.	27.	22.	26.	25.	
19210 P	22.	21.	21.	15.	22.	26.	28.	12.	29.	20.	26.	23.	26.	
19211 P	17.	24.	21.	20.	21.	29.	27.	18.	27.	16.	25.	23.	27.	
19212 P	25.	23.	22.	23.	28.	34.	13.	31.	21.	29.	25.	32.	28.	
19213 P	24.	25.	22.	27.	27.	27.	19.	34.	22.	30.	25.	31.	24.	
19215 P	23.	27.	27.	16.	23.	30.	34.	24.	33.	20.	30.	27.	29.	
19216 P	23.	20.	25.	19.	21.	25.	28.	15.	28.	17.	25.	20.	26.	
19218 P	20.	20.	21.	18.	21.	25.	22.	13.	26.	18.	23.	21.	29.	
19219 P	24.	24.	26.	25.	26.	26.	18.	29.	22.	26.	21.	30.	26.	
19220 P	24.	22.	19.	19.	27.	19.	12.	25.	13.	24.	24.	29.	22.	
-----														

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B31 (PAGE 10): MATERNAL FEED CONSUMPTION VALUES - PRESUMED GESTATION - INDIVIDUAL DATA - PART D

PREGNANCY								
STATUS DAYS 13 - 14 14 - 15 15 - 16 16 - 17 17 - 18 18 - 19 19 - 20 20 - 21								
RAT #	DOSAGE GROUP V 30.0 MG/KG/DAY							
19197 P	21.	25.	25.	24.	26.	23.	26.	20.
19198 P	27.	21.	20.	26.	29.	23.	27.	20.
19199 P	24.	23.	29.	24.	29.	28.	23.	4.
19200 P	24.	23.	25.	30.	21.	29.	28.	27.
19201 P	25.	26.	28.	27.	23.	29.	26.	27.
19202 P	29.	29.	26.	33.	40.	35.	27.	27.
19204 P	27.	26.	31.	28.	28.	27.	24.	19.
19205 P	27.	26.	21.	33.	28.	27.	30.	24.
19206 P	26.	25.	25.	27.	27.	26.	28.	26.
19207 P	20.	23.	26.	25.	23.	26.	24.	24.
19208 P	22.	23.	25.	30.	24.	28.	22.	22.
19210 P	21.	20.	24.	26.	31.	25.	27.	27.
19211 P	17.	20.	23.	25.	37.	21.	31.	24.
19212 P	25.	24.	30.	31.	26.	31.	26.	30.
19213 P	25.	28.	29.	33.	25.	30.	30.	29.
19215 P	33.	30.	31.	31.	32.	33.	31.	27.
19216 P	26.	19.	25.	24.	31.	24.	27.	23.
19218 P	25.	22.	27.	31.	26.	29.	27.	25.
19219 P	21.	26.	27.	30.	26.	34.	25.	28.
19220 P	22.	22.	24.	25.	19.	27.	23.	22.

P = PREGNANT NP = NOT PREGNANT (VALUES EXCLUDED FROM AVERAGES)

DAYS = DAYS OF PRESUMED GESTATION

ALL WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B32 (PAGE 1): CAESAREAN-SECTIONING OBSERVATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP I			0 (CARRIER) MG/KG/DAY																	
VIABLE FETUSES						DEAD FETUSES			EARLY RESORPTIONS		LATE RESORPTIONS		IMPLANTATION SITES				CORPORA LUTEA			
RAT #	SEX		RIGHT LEFT			RIGHT LEFT			RIGHT LEFT		RIGHT LEFT		RIGHT LEFT		RIGHT LEFT		RIGHT LEFT			
	M	F	HORN		TOTAL	HORN		TOTAL	HORN	TOTAL	HORN	TOTAL	HORN	TOTAL	HORN	TOTAL	OVARY	TOTAL		
19101	9	10	9	10	19	0	0	0	0	0	0	0	0	9	10	19	9	10	19	
19102	7	10	8	9	17	0	0	0	1	0	1	0	0	9	9	18	10	11	21	
19103	7	9	10	6	16	0	0	0	0	0	0	0	0	10	6	16	11	6	17	
19104	7	8	9	6	15	0	0	0	0	0	0	0	0	9	6	15	9	6	15	
19105	6	11	10	7	17	0	0	0	0	0	0	0	0	10	7	17	12	7	19	
19107	7	7	4	10	14	0	0	0	0	0	0	0	0	4	10	14	6	13	19	
19108	5	11	9	7	16	0	0	0	0	0	0	0	0	9	7	16	10	10	20	
19109	5	11	8	8	16	0	0	0	0	0	0	0	0	8	8	16	13	15	28	
19110	9	10	10	9	19	0	0	0	0	0	0	0	0	10	9	19	10	12	22	
19111	6	10	5	11	16	0	0	0	1	0	1	0	0	6	11	17	6	12	18	
19112	12	6	10	8	18	0	0	0	0	0	0	0	0	10	8	18	10	9	19	
19113	8	8	8	8	16	0	0	0	0	0	0	0	0	8	8	16	10	9	19	
19114	9	6	10	5	15	0	0	0	0	0	0	0	0	10	5	15	10	5	15	
19115	9	10	8	11	19	0	0	0	0	0	0	0	0	8	11	19	8	11	19	
19116	10	6	8	8	16	0	0	0	1	0	1	0	0	9	8	17	10	8	18	
19117	8	9	11	6	17	0	0	0	0	0	0	0	0	11	6	17	12	8	20	
19119	9	10	10	9	19	0	0	0	1	0	1	0	0	11	9	20	11	10	21	
19120	NOT PREGNANT																			
19123	9	6	9	6	15	0	0	0	1	1	2	0	0	10	7	17	12	8	20	
19124	7	9	7	9	16	0	0	0	1	0	1	0	0	8	9	17	8	9	17	

M = MALE F = FEMALE

PLACENTAE APPEARED NORMAL UNLESS NOTED OTHERWISE.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B32 (PAGE 2): CAESAREAN-SECTIONING OBSERVATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP II						0.01 MG/KG/DAY														
VIABLE FETUSES						DEAD FETUSES			EARLY RESORPTIONS		LATE RESORPTIONS			IMPLANTATION SITES			CORPORA LUTEA			
RAT #	SEX		RIGHT LEFT		TOTAL	RIGHT LEFT		TOTAL	RIGHT LEFT		TOTAL	RIGHT LEFT		TOTAL	RIGHT LEFT		TOTAL	RIGHT LEFT		TOTAL
	M	F	HORN			HORN			HORN			HORN			HORN			HORN		
19125	10	6	6	10	16	0	0	0	0	1	1	0	0	0	6	11	17	6	13	19
19127	NOT PREGNANT																			
19128	7	12	11	8	19	0	0	0	0	0	0	0	0	0	11	8	19	11	8	19
19130	10	5	7	8	15	0	0	0	0	0	0	0	0	0	7	8	15	8	8	16
19131	6	6	8	4	12	0	0	0	0	0	0	0	0	0	8	4	12	9	5	14
19132	7	10	8	9	17	0	0	0	0	0	0	0	0	0	8	9	17	8	11	19
19133	6	8	8	6	14	0	0	0	1	0	1	0	0	0	9	6	15	9	10	19
19134	9	6	9	6	15	0	0	0	0	0	0	0	0	0	9	6	15	9	6	15
19135	7	9	9	7	16	0	0	0	2	0	2	0	0	0	11	7	18	12	8	20
19136	8	8	8	8	16	0	0	0	0	0	0	0	0	0	8	8	16	9	10	19
19137	4	6	9	1	10	0	0	0	0	0	0	1	0	1	10	1	11	10	5	15
19139	8	9	7	10	17	0	0	0	0	0	0	0	0	0	7	10	17	8	10	18
19140	7	11	8	10	18	0	0	0	0	0	0	0	0	0	8	10	18	10	12	22
19141	4	8	5	7	12	0	0	0	0	0	0	0	0	0	5	7	12	8	9	17
19143	2	1	1	2	3	0	0	0	0	0	0	0	0	0	1	2	3	6	14	20
19144	11	6	11	6	17	0	0	0	0	0	0	0	0	0	11	6	17	11	9	20
19145	12	3	10	5	15	0	0	0	0	0	0	0	0	0	10	5	15	10	8	18
19146	8	4	3	9	12	0	0	0	2	1	3	0	0	0	5	10	15	5	10	15
19147	4	12	11	5	16	0	0	0	0	1	1	0	0	0	11	6	17	11	9	20
19148	10	1	5	6	11	0	0	0	0	0	0	0	0	0	5	6	11	7	8	15

M = MALE F = FEMALE

PLACENTAE APPEARED NORMAL UNLESS NOTED OTHERWISE.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B32 (PAGE 3): CAESAREAN-SECTIONING OBSERVATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP III			0.1 MG/KG/DAY																	
RAT #	SEX		VIABLE FETUSES			DEAD FETUSES			EARLY RESORPTIONS			LATE RESORPTIONS			IMPLANTATION SITES			CORPORA LUTEA		
	M	F	RIGHT HORN	LEFT HORN	TOTAL	RIGHT HORN	LEFT HORN	TOTAL	RIGHT HORN	LEFT HORN	TOTAL	RIGHT HORN	LEFT HORN	TOTAL	RIGHT HORN	LEFT HORN	TOTAL	RIGHT OVARY	LEFT OVARY	TOTAL
19150	9	8	11	6	17	0	0	0	0	0	0	0	0	0	11	6	17	11	8	19
19151	2	5	7	0	7	0	0	0	0	0	0	0	0	0	7	0	7	9	5	14
19152	10	6	8	8	16	0	0	0	0	0	0	0	0	0	8	8	16	9	9	18
19153	NOT PREGNANT																			
19155	4	7	8	3	11	0	0	0	0	2	2	0	0	0	8	5	13	10	6	16
19156	NOT PREGNANT																			
19157	5	8	7	6	13	0	0	0	0	0	0	0	0	0	7	6	13	7	9	16
19158	7	11	10	8	18	0	0	0	0	0	0	0	0	0	10	8	18	10	9	19
19159	9	7	5	11	16	0	0	0	1	0	1	0	0	0	6	11	17	10	12	22
19160	8	1	1	8	9	0	0	0	0	0	0	0	0	0	1	8	9	5	11	16
19161	10	7	9	8	17	0	0	0	1	1	2	0	0	0	10	9	19	11	12	23
19162	12	6	8	10	18	0	0	0	0	0	0	0	0	0	8	10	18	8	10	18
19164	7	10	8	9	17	0	0	0	0	0	0	0	0	0	8	9	17	8	13	21
19165	8	8	9	7	16	0	0	0	0	0	0	0	0	0	9	7	16	11	9	20
19166	NOT PREGNANT																			
19167	7	10	7	10	17	0	0	0	0	0	0	0	0	0	7	10	17	8	11	19
19168	4	7	6	5	11	0	0	0	0	0	0	0	0	0	6	5	11	11	9	20
19170	9	6	8	7	15	0	0	0	1	0	1	0	0	0	9	7	16	9	7	16
19171	7	8	10	5	15	0	0	0	1	0	1	0	0	0	11	5	16	11	5	16
19172	0	3	0	3	3	0	0	0	1	0	1	0	0	0	1	3	4	11	4	15

M = MALE F = FEMALE

PLACENTAE APPEARED NORMAL UNLESS NOTED OTHERWISE.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B32 (PAGE 4): CAESAREAN-SECTIONING OBSERVATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP IV			1.0 MG/KG/DAY																	
RAT #	SEX		VIABLE FETUSES			DEAD FETUSES			EARLY RESORPTIONS			LATE RESORPTIONS			IMPLANTATION SITES			CORPORA LUTEA		
	M	F	RIGHT HORN	LEFT HORN	TOTAL	RIGHT HORN	LEFT HORN	TOTAL	RIGHT HORN	LEFT HORN	TOTAL	RIGHT HORN	LEFT HORN	TOTAL	RIGHT HORN	LEFT HORN	TOTAL	RIGHT OVARY	LEFT OVARY	TOTAL
19173	6	13	10	9	19	0	0	0	0	0	0	0	0	0	10	9	19	10	9	19
19174	10	10	12	8	20	0	0	0	0	0	0	0	0	0	12	8	20	12	8	20
19175	13	4	9	8	17	0	0	0	0	0	0	0	0	0	9	8	17	9	10	19
19176	7	7	5	9	14	0	0	0	1	0	1	0	0	0	6	9	15	6	9	15
19177	5	7	8	4	12	0	0	0	0	0	0	0	0	0	8	4	12	8	6	14
19178	6	9	9	6	15	0	0	0	1	0	1	0	0	0	10	6	16	10	12	22
19179	8	8	10	6	16	0	0	0	0	2	2	0	0	0	10	8	18	11	8	19
19180	8	11	13	6	19	0	0	0	0	1	1	0	0	0	13	7	20	16	12	28
19181	7	10	7	10	17	0	0	0	0	0	0	0	0	0	7	10	17	13	12	25
19182	5	12	7	10	17	0	0	0	0	0	0	0	0	0	7	10	17	9	11	20
19184	12	6	10	8	18	0	0	0	0	0	0	0	0	0	10	8	18	10	9	19
19185	11	7	7	11	18	0	0	0	0	0	0	0	0	0	7	11	18	8	11	19
19186	11	6	7	10	17	0	0	0	0	0	0	0	0	0	7	10	17	9	12	21
19187	9	7	9	7	16	0	0	0	0	0	0	0	0	0	9	7	16	9	8	17
19188	6	10	7	9	16	0	0	0	1	0	1	0	0	0	8	9	17	9	10	19
19189	3	1	2	2	4	0	0	0	0	0	0	0	0	0	2	2	4	7	12	19
19190	9	13	11	11	22	0	0	0	0	0	0	0	0	0	11	11	22	11	11	22
19191	9	9	8	10	18	0	0	0	0	0	0	0	0	0	8	10	18	8	10	18
19193	8	7	8	7	15	0	0	0	0	0	0	0	0	0	8	7	15	9	10	19
19196	9	6	6	9	15	0	0	0	1	1	2	0	0	0	7	10	17	11	11	22

M = MALE      F = FEMALE  
PLACENTAE APPEARED NORMAL UNLESS NOTED OTHERWISE.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B32 (PAGE 5): CAESAREAN-SECTIONING OBSERVATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP V			30.0 MG/KG/DAY																	
VIABLE FETUSES					DEAD FETUSES			EARLY RESORPTIONS		LATE RESORPTIONS		IMPLANTATION SITES			CORPORA LUTEA					
RAT #	SEX		RIGHT LEFT		TOTAL	RIGHT LEFT		TOTAL	RIGHT LEFT		TOTAL	RIGHT LEFT		TOTAL	RIGHT LEFT		TOTAL	RIGHT LEFT		TOTAL
	M	F	HORN			HORN			HORN			HORN			HORN			HORN		
19197	8	8	8	8	16	0	0	0	1	0	1	0	0	0	9	8	17	10	8	18
19198	7	6	8	5	13	0	0	0	2	1	3	0	0	0	10	6	16	10	6	16
19199	8	6	8	6	14	0	0	0	0	1	1	0	0	0	8	7	15	15	13	28
19200	6	9	9	6	15	0	0	0	1	2	3	0	0	0	10	8	18	11	9	20
19201	6	9	13	2	15	0	0	0	0	0	0	0	0	0	13	2	15	14	4	18
19202	7	3	2	8	10	0	0	0	0	0	0	0	0	0	2	8	10	11	14	25
19204	8	12	10	10	20	0	0	0	0	0	0	0	0	0	10	10	20	11	11	22
19205	5	10	9	6	15	0	0	0	0	1	1	0	0	0	9	7	16	13	11	24
19206	6	8	7	7	14	0	0	0	1	0	1	0	0	0	8	7	15	9	9	18
19207	8	5	7	6	13	0	0	0	0	0	0	0	0	0	7	6	13	7	6	13
19208	10	6	10	6	16	0	0	0	0	0	0	0	0	0	10	6	16	10	9	19
19210	6	6	8	4	12	0	0	0	0	0	0	0	0	0	8	4	12	10	6	16
19211	6	10	8	8	16	0	0	0	1	0	1	0	0	0	9	8	17	9	10	19
19212	8	10	8	10	18	0	0	0	0	1	1	0	0	0	8	11	19	14	14	28
19213	9	6	9	6	15	0	0	0	1	1	2	0	0	0	10	7	17	10	8	18
19215	0	1	1	0	1	0	0	0	0	1	1	0	0	0	1	1	2	9	4	13
19216	3	9	5	7	12	0	0	0	0	0	0	0	0	0	5	7	12	10	8	18
19218	14	3	9	8	17	0	0	0	0	0	0	0	0	0	9	8	17	12	11	23
19219	9	7	7	9	16	0	0	0	0	0	0	0	0	0	7	9	16	8	11	19
19220	7	7	11	3	14	0	0	0	0	0	0	0	0	0	11	3	14	12	10	22

M = MALE F = FEMALE

PLACENTAE APPEARED NORMAL UNLESS NOTED OTHERWISE.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B33 (PAGE 1): LITTER OBSERVATIONS (CAESAREAN-DELIVERED FETUSES) - INDIVIDUAL DATA - PART D

DOSAGE GROUP I			0 (CARRIER) MG/KG/DAY						
RAT #	NUMBER OF LIVE FETUSES			AVERAGE FETAL BODY WEIGHT (G)			---- CONCEPTUSES -----		
	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL a	N	N	%
19101	9	10	19	4.28	4.09	4.18	19	0	0.0
19102	7	10	17	4.06	3.78	3.90	18	1	5.6
19103	7	9	16	4.66	4.19	4.40	16	0	0.0
19104	7	8	15	4.38	4.17	4.27	15	0	0.0
19105	6	11	17	4.45	4.26	4.33	17	0	0.0
19107	7	7	14	4.34	4.17	4.25	14	0	0.0
19108	5	11	16	4.39	4.24	4.29	16	0	0.0
19109	5	11	16	4.43	4.39	4.40	16	0	0.0
19110	9	10	19	4.26	4.28	4.27	19	0	0.0
19111	6	10	16	4.23	3.96	4.06	17	1	5.9
19112	12	6	18	4.06	3.94	4.02	18	0	0.0
19113	8	8	16	4.86	4.65	4.76	16	0	0.0
19114	9	6	15	4.69	4.35	4.56	15	0	0.0
19115	9	10	19	4.40	4.23	4.31	19	0	0.0
19116	10	6	16	4.54	4.23	4.42	17	1	5.9
19117	8	9	17	4.21	4.06	4.13	17	0	0.0
19119	9	10	19	4.40	4.13	4.26	20	1	5.0
19120	NOT PREGNANT								
19123	9	6	15	4.50	4.31	4.42	17	2	11.8
19124	7	9	16	4.56	4.39	4.46	17	1	5.9

a. TOTAL = SUM OF FETAL WEIGHTS/NUMBER OF LIVE FETUSES.



PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B33 (PAGE 2): LITTER OBSERVATIONS (CAESAREAN-DELIVERED FETUSES) - INDIVIDUAL DATA - PART D

DOSAGE GROUP II			0.01 MG/KG/DAY						
RAT #	NUMBER OF LIVE FETUSES			AVERAGE FETAL BODY WEIGHT (G)			---- CONCEPTUSES -----		
	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL a	N	N	%
19125	10	6	16	4.53	4.25	4.42	17	1	5.9
19127	NOT PREGNANT								
19128	7	12	19	4.50	4.25	4.34	19	0	0.0
19130	10	5	15	4.40	4.05	4.29	15	0	0.0
19131	6	6	12	4.50	4.15	4.32	12	0	0.0
19132	7	10	17	4.13	3.89	3.99	17	0	0.0
19133	6	8	14	4.85	4.54	4.67	15	1	6.7
19134	9	6	15	4.37	4.00	4.22	15	0	0.0
19135	7	9	16	3.94	3.75	3.83	18	2	11.1
19136	8	8	16	4.43	4.08	4.25	16	0	0.0
19137	4	6	10	4.78	4.46	4.59	11	1	9.1
19139	8	9	17	4.59	4.06	4.31	17	0	0.0
19140	7	11	18	5.08	4.96	5.01	18	0	0.0
19141	4	8	12	5.38	5.13	5.21	12	0	0.0
19143	2	1	3	5.30	4.50	5.03	3	0	0.0
19144	11	6	17	4.13	4.09	4.12	17	0	0.0
19145	12	3	15	4.58	4.28	4.52	15	0	0.0
19146	8	4	12	4.90	4.59	4.80	15	3	20.0
19147	4	12	16	4.20	4.04	4.08	17	1	5.9
19148	10	1	11	4.62	4.30	4.59	11	0	0.0

a. TOTAL = SUM OF FETAL WEIGHTS/NUMBER OF LIVE FETUSES.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B33 (PAGE 3): LITTER OBSERVATIONS (CAESAREAN-DELIVERED FETUSES) - INDIVIDUAL DATA - PART D

DOSAGE GROUP III			0.1 MG/KG/DAY						
RAT #	NUMBER OF LIVE FETUSES			AVERAGE FETAL BODY WEIGHT (G)			---- CONCEPTUSES ----- RESORBED		
	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL a	N	N	%
19150	9	8	17	4.43	3.89	4.17	17	0	0.0
19151	2	5	7	4.78	4.55	4.62	7	0	0.0
19152	10	6	16	4.50	4.07	4.34	16	0	0.0
19153	NOT PREGNANT								
19155	4	7	11	4.60	4.49	4.53	13	2	15.4
19156	NOT PREGNANT								
19157	5	8	13	4.77	4.56	4.64	13	0	0.0
19158	7	11	18	4.70	4.48	4.57	18	0	0.0
19159	9	7	16	4.45	3.93	4.22	17	1	5.9
19160	8	1	9	6.53	6.39	6.51	9	0	0.0
19161	10	7	17	4.24	4.11	4.19	19	2	10.5
19162	12	6	18	4.72	4.47	4.64	18	0	0.0
19164	7	10	17	4.59	4.39	4.47	17	0	0.0
19165	8	8	16	4.57	4.25	4.41	16	0	0.0
19166	NOT PREGNANT								
19167	7	10	17	4.48	4.24	4.34	17	0	0.0
19168	4	7	11	4.86	4.83	4.84	11	0	0.0
19170	9	6	15	4.73	4.35	4.58	16	1	6.2
19171	7	8	15	4.91	4.80	4.85	16	1	6.2
19172	0	3	3	----	4.57	4.57	4	1	25.0

a. TOTAL = SUM OF FETAL WEIGHTS/NUMBER OF LIVE FETUSES.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B33 (PAGE 4): LITTER OBSERVATIONS (CAESAREAN-DELIVERED FETUSES) - INDIVIDUAL DATA - PART D

DOSAGE GROUP IV			1.0 MG/KG/DAY						
RAT #	NUMBER OF LIVE FETUSES			AVERAGE FETAL BODY WEIGHT (G)			---- CONCEPTUSES -----		
	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL a	N	N	%
19173	6	13	19	4.16	3.90	3.98	19	0	0.0
19174	10	10	20	4.77	4.57	4.67	20	0	0.0
19175	13	4	17	5.14	4.87	5.07	17	0	0.0
19176	7	7	14	4.72	4.19	4.46	15	1	6.7
19177	5	7	12	4.56	4.39	4.46	12	0	0.0
19178	6	9	15	5.22	4.99	5.08	16	1	6.2
19179	8	8	16	4.26	4.00	4.13	18	2	11.1
19180	8	11	19	4.90	4.56	4.70	20	1	5.0
19181	7	10	17	4.90	4.57	4.70	17	0	0.0
19182	5	12	17	4.52	4.23	4.31	17	0	0.0
19184	12	6	18	4.83	4.51	4.72	18	0	0.0
19185	11	7	18	4.59	4.12	4.40	18	0	0.0
19186	11	6	17	4.66	4.16	4.48	17	0	0.0
19187	9	7	16	4.48	4.16	4.34	16	0	0.0
19188	6	10	16	4.43	4.16	4.26	17	1	5.9
19189	3	1	4	5.27	4.85	5.16	4	0	0.0
19190	9	13	22	4.58	4.48	4.52	22	0	0.0
19191	9	9	18	4.57	4.43	4.50	18	0	0.0
19193	8	7	15	4.78	4.52	4.66	15	0	0.0
19196	9	6	15	4.34	4.27	4.31	17	2	11.8

a. TOTAL = SUM OF FETAL WEIGHTS/NUMBER OF LIVE FETUSES.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B33 (PAGE 5): LITTER OBSERVATIONS (CAESAREAN-DELIVERED FETUSES) - INDIVIDUAL DATA - PART D

DOSAGE GROUP V			30.0 MG/KG/DAY						
RAT #	NUMBER OF LIVE FETUSES			AVERAGE FETAL BODY WEIGHT (G)			---- CONCEPTUSES ----- RESORBED		
	MALE	FEMALE	TOTAL	MALE	FEMALE	TOTAL a	N	N	%
19197	8	8	16	4.45	4.24	4.34	17	1	5.9
19198	7	6	13	4.77	4.49	4.64	16	3	18.8
19199	8	6	14	4.34	4.08	4.23	15	1	6.7
19200	6	9	15	3.46	3.47	3.47	18	3	16.7
19201	6	9	15	4.42	4.00	4.17	15	0	0.0
19202	7	3	10	4.19	3.86	4.09	10	0	0.0
19204	8	12	20	4.57	4.42	4.48	20	0	0.0
19205	5	10	15	4.21	4.18	4.19	16	1	6.2
19206	6	8	14	3.91	4.03	3.98	15	1	6.7
19207	8	5	13	4.75	4.81	4.77	13	0	0.0
19208	10	6	16	4.30	3.85	4.13	16	0	0.0
19210	6	6	12	4.91	4.80	4.86	12	0	0.0
19211	6	10	16	4.67	4.41	4.51	17	1	5.9
19212	8	10	18	4.30	4.14	4.21	19	1	5.3
19213	9	6	15	5.12	4.65	4.93	17	2	11.8
19215	0	1	1	----	6.93	6.93	2	1	50.0
19216	3	9	12	4.86	4.34	4.47	12	0	0.0
19218	14	3	17	4.88	4.52	4.81	17	0	0.0
19219	9	7	16	4.31	3.97	4.16	16	0	0.0
19220	7	7	14	4.69	4.31	4.50	14	0	0.0

a. TOTAL = SUM OF FETAL WEIGHTS/NUMBER OF LIVE FETUSES.

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B34 (PAGE 1): FETAL SEX, VITAL STATUS AND BODY WEIGHT - INDIVIDUAL DATA - PART D

DOSAGE GROUP I		0 (CARRIER) MG/KG/DAY																						
FETUS #		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
RAT #	CLs																							
19101	9/10	FA	FA	MA	FA	FA	FA	FA	MA	FA / MA	MA	MA	FA	FA	MA	MA	MA	FA	MA					
		3.80	3.92	4.22	4.25	4.34	4.09	4.27	4.13	4.26	4.13	4.52	4.20	4.05	3.91	4.39	4.37	4.33	4.01	4.24				
19102	10/11	FA	FA	MA	FA	MA	FA	E	FA	MA / MA	FA	FA	FA	MA	FA	MA	MA	FA						
		3.37	3.69	4.18	4.00	4.28	3.61		3.57	4.18	3.81	4.25	3.68	3.73	4.22	3.90	3.94	3.84	3.98					
19103	11/ 6	MA	MA	FA	MA	FA	FA	FA	FA	FA / MA	FA	MA	MA	FA	MA	FA	MA							
		4.54	4.66	4.09	4.31	4.30	4.06	4.09	3.89	4.10	4.80	4.97	4.48	4.87	4.83	3.92	4.47							
19104	9/ 6	MA	MA	FA	FA	FA	FA	MA	FA	MA / FA	MA	MA	FA	MA	FA									
		4.51	4.17	4.09	4.23	4.19	3.95	4.25	4.38	4.53	4.24	4.40	4.42	4.01	4.41	4.26								
19105	12/ 7	MA	MA	FA	FA	FA	FA	MA	FA	FA / FA	MA	FA	MA	FA	MA	MA	FA	FA						
		4.44	4.61	4.10	4.19	4.62	4.26	4.46	3.94	4.40	4.43	4.22	4.62	3.77	4.30	4.25	4.48	4.47						
19107	6/13	FA	FA	MA	FA / MA	FA	MA	MA	FA	FA	MA	MA	FA	MA										
		4.65	4.12	4.57	4.01	4.43	4.11	4.19	4.40	4.16	4.10	4.57	3.88	4.03	4.33									
19108	10/10	FA	FA	MA	MA	FA	FA	FA	FA	MA / FA	FA	FA	FA	FA	MA	FA	MA							
		4.05	4.47	4.17	4.43	4.11	4.07	4.25	4.46	4.50	4.12	4.49	4.07	4.22	4.28	4.35	4.59							
19109	13/15	MA	FA	FA	FA	FA	MA	FA	FA / FA	FA	MA	FA	FA	FA	MA	FA	MA							
		4.60	4.51	4.39	4.09	4.48	4.45	4.61	4.41	4.41	4.58	4.23	3.97	4.58	4.62	4.23	4.27							
19110	10/12	FA	MA	FA	MA	FA	FA	MA	FA	FA / MA	FA	MA	MA	MA	MA	MA	MA	FA	FA	MA				
		4.30	4.01	4.17	4.47	4.24	4.44	4.14	4.21	4.62	3.95	4.02	3.80	4.12	4.37	4.57	4.26	4.47	4.58	4.38				
19111	6/12	FA	FA	FA	E	FA	FA / FA	FA	MA	MA	MA	MA	FA	FA	FA	MA	MA							
		3.56	4.20	4.49		3.79	4.50	3.30	4.21	3.99	4.20	4.45	3.98	3.88	3.77	3.93	4.31	4.43						
19112	10/ 9	FA	MA	FA	MA	MA	FA	MA	MA	MA / MA	MA	MA	FA	FA	MA	MA	MA	FA	MA					
		4.09	4.30	4.00	4.24	4.09	4.02	4.07	3.95	4.19	4.22	4.01	3.89	3.92	3.52	4.04	3.82	4.12	3.92					
19113	10/ 9	MA	MA	MA	FA	MA	MA	FA	FA / FA	FA	FA	FA	FA	MA	FA	MA	MA							
		5.00	4.90	4.42	4.58	4.90	4.91	4.59	4.47	4.76	4.45	4.75	4.90	5.02	4.68	4.38	5.38							

M = MALE F = FEMALE A = ALIVE E = EARLY RESORPTION L = LATE RESORPTION "/" DENOTES POSITION OF CERVIX  
CLs = CORPORA LUTEA/OVARY FETAL BODY WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B34 (PAGE 2): FETAL SEX, VITAL STATUS AND BODY WEIGHT - INDIVIDUAL DATA - PART D

DOSAGE GROUP I				0 (CARRIER) MG/KG/DAY																				
FETUS #		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
RAT #	CLs																							
19114	10/ 5	MA	FA	MA	MA	MA	FA	FA	FA	MA	FA / MA	MA	MA	FA	MA									
		4.79	4.71	4.45	4.57	4.58	4.38	4.37	4.09	4.58	4.44	5.13	4.33	4.70	4.13	5.10								
19115	8/11	MA	FA	FA	MA	MA	FA	FA	MA / MA	FA	FA	FA	FA	FA	MA	MA	FA	MA						
		4.33	4.32	4.15	4.50	4.70	4.26	4.48	4.58	4.28	4.03	4.18	4.34	3.99	4.39	4.56	4.04	4.38	4.12	4.22				
19116	10/ 8	MA	MA	FA	E	MA	MA	MA	FA	FA / MA	MA	FA	MA	MA	FA	MA	FA							
		4.47	4.37	4.24		4.62	4.68	4.55	4.44	4.14	4.69	4.44	4.19	4.44	4.62	4.20	4.54	4.15						
19117	12/ 8	FA	MA	FA	MA	MA	FA	MA	FA	FA	MA	MA / MA	FA	MA	FA	FA	FA							
		4.08	4.40	3.87	3.66	4.38	3.97	4.26	4.12	4.01	4.11	4.33	4.25	3.91	4.29	4.07	4.02	4.49						
19119	11/10	MA	MA	E	FA	MA	MA	FA	FA	FA	MA	MA / FA	FA	FA	MA	FA	MA	FA	MA	FA				
		4.22	4.29		4.21	4.45	4.54	4.24	4.38	4.01	4.46	4.38	4.16	3.74	3.71	4.56	4.43	4.49	4.20	4.21	4.25			
19120		NOT PREGNANT																						
19123	12/ 8	MA	MA	MA	MA	FA	MA	MA	FA	FA	E / FA	FA	MA	FA	E	MA	MA							
		4.40	4.83	4.61	3.98	4.45	4.58	3.98	4.21	4.10		4.14	4.34	4.74	4.62		4.68	4.70						
19124	8/ 9	MA	FA	FA	FA	E	FA	MA	MA / FA	MA	MA	FA	MA	FA	FA	MA	FA							
		4.47	4.41	4.55	4.38		4.52	4.87	4.52	3.90	4.80	4.57	4.24	4.35	4.78	4.05	4.37	4.66						
M = MALE    F = FEMALE    A = ALIVE    E = EARLY RESORPTION    L = LATE RESORPTION    "/" DENOTES POSITION OF CERVIX																								
CLs = CORPORA LUTEA/OVARY        FETAL BODY WEIGHTS WERE RECORDED IN GRAMS (G).																								

M = MALE F = FEMALE A = ALIVE E = EARLY RESORPTION L = LATE RESORPTION "/" DENOTES POSITION OF CERVIX  
CLs = CORPORA LUTEA/OVARY FETAL BODY WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B34 (PAGE 3): FETAL SEX, VITAL STATUS AND BODY WEIGHT - INDIVIDUAL DATA - PART D

DOSAGE GROUP II			0.01 MG/KG/DAY																							
FETUS #			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	
RAT #	CLs		MA	FA	MA	FA	FA	MA / MA	MA	MA	FA	FA	MA	E	FA	MA	MA	MA								
19125	6/13		4.50	4.42	4.76	4.49	4.22	4.55	4.55	4.24	4.55	4.15	4.04	4.31		4.18	4.59	4.50	4.74							
19127			NOT PREGNANT																							
19128	11/ 8		FA	MA	FA	FA	MA	FA	FA	FA	MA	FA	MA / FA	FA	MA	FA	FA	FA	FA	MA	MA					
			4.37	4.51	3.94	4.43	4.74	4.10	4.65	4.07	3.88	4.21	4.90	4.45	4.32	4.49	4.07	4.26	4.17	4.55	4.40					
19130	8/ 8		MA	MA	MA	FA	MA	MA	MA / MA	MA	FA	FA	MA	FA	MA	FA										
			4.11	4.39	4.19	4.10	4.32	4.66	4.63	4.88	4.24	4.06	3.97	4.16	4.02	4.44	4.12									
19131	9/ 5		MA	MA	FA	MA	FA	FA	MA / FA	FA	FA	MA	MA													
			4.47	4.42	4.27	4.69	4.14	4.27	4.00	4.32	4.10	4.14	4.46	4.62												
19132	8/11		FA	FA	FA	MA	FA	FA	MA	MA / MA	MA	FA	FA	FA	FA	FA	MA	MA	FA							
			4.03	3.68	3.85	4.38	4.08	3.89	4.02	4.07	4.22	4.01	4.13	4.08	3.91	3.76	4.21	4.02	3.51							
19133	9/10		FA	FA	MA	FA	E	FA	MA	FA	MA / MA	FA	FA	FA	FA	MA	MA									
			4.53	4.88	4.81	4.34		4.48	4.55	4.36	4.85	4.83	4.53	4.62	4.58	4.84	5.24									
19134	9/ 6		FA	MA	MA	MA	MA	FA	MA	MA	MA / FA	FA	FA	FA	MA	MA	FA									
			4.20	4.15	4.23	4.57	4.71	4.22	4.56	4.41	4.12	3.03	4.26	4.49	4.21	4.35	3.80									
19135	12/ 8		FA	MA	MA	FA	MA	FA	E	E	FA	FA	MA / FA	MA	FA	MA	FA	MA	FA	MA	FA					
			3.91	3.76	3.61	3.80	4.12	4.02			3.34	3.42	3.94	4.10	3.95	3.61	4.03	3.73	4.15	3.86						
19136	9/10		MA	FA	FA	FA	FA	MA	MA	MA / FA	MA	MA	MA	MA	MA	FA	FA	FA								
			4.48	4.06	3.97	4.27	4.36	4.48	4.31	4.54	3.77	4.35	4.56	4.35	4.37	4.09	4.02	4.07								
19137	10/ 5		FA	MA	FA	MA	MA	FA	FL	MA	FA	FA / FA														
			4.28	4.67	4.48	5.07	4.81	4.67	3.47	4.57	4.55	4.43	4.36													

M = MALE F = FEMALE A = ALIVE E = EARLY RESORPTION L = LATE RESORPTION "/" DENOTES POSITION OF CERVIX  
CLs = CORPORA LUTEA/OVARY FETAL BODY WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B34 (PAGE 4): FETAL SEX, VITAL STATUS AND BODY WEIGHT - INDIVIDUAL DATA - PART D

DOSAGE GROUP II				0.01 MG/KG/DAY																				
FETUS #		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
RAT #	CLs																							
19139	8/10	MA	MA	FA	MA	MA	FA	FA /	FA	FA	FA	MA	MA	MA	MA	FA	FA	FA						
		4.62	4.64	3.92	4.35	4.75	4.31	4.46	4.08	4.00	4.07	4.54	4.65	4.72	4.45	4.09	3.85	3.77						
19140	10/12	FA	MA	MA	FA	FA	MA	FA	FA /	MA	FA	FA	FA	MA	FA	FA	MA	MA	FA					
		5.09	5.04	5.37	4.89	5.08	5.01	4.61	5.27	5.12	4.81	5.08	4.79	5.06	4.96	4.97	4.93	5.01	5.05					
19141	8/ 9	FA	FA	MA	FA	MA /	FA	FA	FA	FA	MA	MA	FA											
		5.11	5.07	5.36	5.11	5.40	4.97	4.77	5.44	5.20	5.40	5.34	5.36											
19143	6/14	MA /	FA	MA																				
		5.23	4.50	5.36																				
19144	11/ 9	MA	MA	FA	MA	FA	MA	FA	FA	MA	MA	FA /	FA	MA	MA	MA	MA	MA						
		4.23	3.89	4.27	4.35	3.95	4.16	4.10	3.98	2.60	3.90	3.88	4.38	4.14	4.59	4.66	4.46	4.43						
19145	10/ 8	MA	MA	MA	MA	MA	MA	FA	MA	MA	MA /	MA	FA	MA	MA	FA								
		4.67	4.75	4.63	4.60	4.48	4.44	4.23	4.61	4.60	4.28	4.59	4.24	4.91	4.47	4.37								
19146	5/10	E	FA	E	MA	MA /	MA	MA	MA	FA	MA	E	MA	FA	FA	MA								
			4.82		5.08	4.95	4.53	4.71	4.89	4.37	5.21		4.83	4.72	4.45	5.00								
19147	11/ 9	FA	FA	FA	FA	FA	FA	MA	FA	MA	MA	FA /	MA	FA	FA	E	FA	FA						
		3.90	4.30	3.89	4.19	3.51	4.13	4.39	3.94	4.01	4.04	3.96	4.34	4.05	3.99		4.66	4.00						
19148	7/ 8	MA	MA	MA	MA	MA /	MA	MA	FA	MA	MA	MA												
		4.38	4.85	4.69	4.84	4.57	4.63	4.52	4.30	4.56	4.21	4.98												
M = MALE    F = FEMALE    A = ALIVE    E = EARLY RESORPTION    L = LATE RESORPTION    "/" DENOTES POSITION OF CERVIX																								
CLs = CORPORA LUTEA/OVARY		FETAL BODY WEIGHTS WERE RECORDED IN GRAMS (G).																						

M = MALE F = FEMALE A = ALIVE E = EARLY RESORPTION L = LATE RESORPTION "/" DENOTES POSITION OF CERVIX  
CLs = CORPORA LUTEA/OVARY FETAL BODY WEIGHTS WERE RECORDED IN GRAMS (G).



PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B34 (PAGE 5): FETAL SEX, VITAL STATUS AND BODY WEIGHT - INDIVIDUAL DATA - PART D

DOSAGE GROUP III				0.1 MG/KG/DAY																				
FETUS #		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
RAT #	CLs																							
19150	11/ 8	FA	MA	FA	MA	MA	MA	FA	MA	FA	MA	MA /	FA	MA	FA	FA	MA	FA						
		1.76	4.24	4.07	4.30	4.47	4.82	4.27	4.66	4.16	4.52	4.36	4.03	4.43	4.35	4.22	4.05	4.25						
19151	9/ 5	FA	FA	FA	MA	FA	FA	MA /																
		4.23	4.82	4.77	4.57	4.34	4.61	4.98																
19152	9/ 9	MA	MA	MA	MA	FA	FA	MA	MA /	FA	MA	MA	FA	FA	FA	MA	MA							
		4.13	4.47	4.69	4.71	3.46	4.30	4.49	4.63	4.03	3.92	4.49	3.94	4.54	4.13	4.66	4.83							
19153		NOT PREGNANT																						
19155	10/ 6	FA	MA	FA	MA	FA	FA	FA	MA /	MA	E	FA	E	FA										
		3.97	4.68	4.45	5.12	4.63	4.27	4.59	4.58	4.02		4.78		4.73										
19156		NOT PREGNANT																						
19157	7/ 9	FA	MA	FA	MA	FA	FA	FA /	MA	MA	MA	FA	FA	FA										
		5.00	5.14	4.14	4.83	4.71	4.38	4.28	4.95	4.31	4.63	4.71	4.80	4.49										
19158	10/ 9	MA	FA	FA	FA	MA	MA	FA	FA	MA	FA /	MA	FA	FA	FA	MA	FA	FA	MA					
		4.82	4.58	4.78	4.47	4.50	4.58	4.29	4.43	4.93	4.69	4.47	4.28	4.31	4.18	4.64	4.41	4.88	4.99					
19159	10/12	MA	MA	E	MA	FA	FA /	FA	MA	FA	MA	MA	MA	MA	FA	FA	MA	FA						
		5.02	4.37		4.81	4.27	3.87	3.62	4.06	3.93	4.33	4.42	4.50	4.08	3.61	4.10	4.48	4.13						
19160	5/11	FA /	MA	MA	MA	MA	MA	MA	MA	MA														
		6.39	6.31	6.69	6.78	6.64	6.75	6.07	6.35	6.64														
19161	11/12	MA	FA	FA	MA	FA	MA	MA	MA	FA	E /	FA	MA	FA	MA	FA	MA	MA	E	MA				
		4.04	4.16	4.23	4.55	4.38	4.37	4.36	3.49	4.03		3.72	4.18	4.09	3.99	4.18	4.38	4.60		4.49				
M = MALE F = FEMALE A = ALIVE E = EARLY RESORPTION L = LATE RESORPTION "/" DENOTES POSITION OF CERVIX CLs = CORPORA LUTEA/OVARY FETAL BODY WEIGHTS WERE RECORDED IN GRAMS (G).																								

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B34 (PAGE 6): FETAL SEX, VITAL STATUS AND BODY WEIGHT - INDIVIDUAL DATA - PART D

DOSAGE GROUP III		0.1 MG/KG/DAY																						
FETUS #		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
RAT #	CLs																							
19162	8/10	MA	MA	FA	FA	FA	MA	FA	MA / MA	MA	MA	MA	MA	MA	FA	MA	MA	FA						
		4.81	4.75	4.11	4.47	4.59	4.62	4.70	5.00	4.34	4.41	4.54	4.57	5.09	4.95	4.32	4.68	4.88	4.63					
19164	8/13	MA	FA	FA	FA	FA	FA	FA	MA / FA	FA	FA	FA	MA	MA	MA	FA	MA	MA						
		4.55	4.22	4.49	4.45	4.47	4.53	4.52	4.41	4.31	4.08	4.33	4.42	4.68	4.72	4.47	4.68	4.69						
19165	11/ 9	FA	MA	FA	MA	FA	FA	MA	MA	FA / MA	FA	MA	MA	MA	FA	FA	MA							
		4.09	4.65	4.58	4.60	4.20	4.08	4.53	4.70	4.11	4.59	4.47	4.52	4.63	4.30	4.20	4.33							
19166		NOT PREGNANT																						
19167	8/11	FA	FA	MA	MA	MA	FA	MA / MA	MA	FA	FA	FA	FA	FA	FA	FA	MA	FA						
		4.19	4.24	4.83	4.67	4.56	4.40	4.62	4.64	4.33	4.23	3.78	4.18	4.37	4.31	4.13	3.75	4.54						
19168	11/ 9	FA	MA	MA	FA	FA	MA / FA	FA	FA	FA	MA													
		4.77	4.69	4.75	5.05	5.08	5.06	4.45	4.70	5.04	4.75	4.95												
19170	9/ 7	FA	FA	FA	MA	MA	MA	FA	E / MA	MA	MA	MA	FA	MA	MA	MA	MA							
		4.18	4.27	4.18	4.80	4.67	4.33	4.35	4.63		4.56	4.72	4.54	4.52	5.03	5.01	4.91							
19171	11/ 5	FA	FA	MA	FA	MA	E	FA	FA	MA	MA	MA / MA	MA	FA	FA	FA								
		4.65	4.93	4.88	4.75	4.78		4.73	4.64	4.79	4.82	4.81	4.97	5.31	4.84	4.83	5.01							
19172	11/ 4	E /	FA	FA	FA																			
		4.57	4.55	4.58																				
M = MALE    F = FEMALE    A = ALIVE    E = EARLY RESORPTION    L = LATE RESORPTION    "/" DENOTES POSITION OF CERVIX																								
CLs = CORPORA LUTEA/OVARY      FETAL BODY WEIGHTS WERE RECORDED IN GRAMS (G).																								

M = MALE F = FEMALE A = ALIVE E = EARLY RESORPTION L = LATE RESORPTION "/" DENOTES POSITION OF CERVIX  
CLs = CORPORA LUTEA/OVARY FETAL BODY WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B34 (PAGE 7): FETAL SEX, VITAL STATUS AND BODY WEIGHT - INDIVIDUAL DATA - PART D

DOSAGE GROUP IV		1.0 MG/KG/DAY																						
FETUS #		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
RAT #	CLs																							
19173	10/ 9	FA	FA	MA	FA	MA	FA	FA	MA	MA	FA / FA	MA	FA	FA	FA	FA	FA	MA	FA	FA				
		3.64	3.07	4.40	3.64	4.09	4.26	3.96	3.94	4.31	4.25	3.72	3.96	4.26	3.81	3.84	3.85	4.26	4.16	4.23				
19174	12/ 8	MA	MA	MA	FA	MA	FA	FA	MA	FA	MA	FA	MA / MA	FA	MA	MA	FA	FA	MA	FA	FA			
		4.72	4.47	5.08	4.61	4.59	4.43	4.72	4.91	4.45	4.76	4.61	4.86	4.72	4.38	5.01	4.46	4.69	4.59	4.36	5.00			
19175	9/10	MA	MA	MA	FA	MA	FA	MA	MA	MA / MA	FA	MA	MA	MA	MA	MA	FA	MA						
		5.09	5.25	5.26	4.79	5.16	4.93	4.93	4.94	5.20	5.09	4.82	5.08	5.15	5.37	4.96	4.94	5.29						
19176	6/ 9	MA	E	MA	FA	FA	FA / MA	MA	MA	MA	FA	FA	FA	FA	MA	MA								
		4.41		4.73	4.12	4.29	4.20	4.43	5.14	4.96	3.75	4.30	4.37	4.32	4.78	4.59								
19177	8/ 6	FA	MA	FA	MA	MA	FA	FA	FA / MA	FA	FA	FA	MA											
		4.23	4.64	4.44	4.47	4.45	4.11	4.20	4.60	4.83	4.50	4.65	4.43											
19178	10/12	MA	E	MA	FA	FA	FA	FA	FA	FA	MA / FA	FA	MA	MA	MA	FA								
		5.17		5.30	5.11	5.07	4.87	5.07	5.00	5.04	5.17	5.05	5.05	5.69	5.04	4.93	4.64							
19179	11/ 8	FA	FA	FA	FA	FA	MA	MA	MA	MA	MA / E	E	E	FA	FA	FA	MA	MA	MA					
		3.73	4.30	4.04	3.98	4.13	4.40	4.01	4.16	4.16	4.51			4.07	3.91	3.81	4.23	4.23	4.40					
19180	16/12	FA	FA	FA	FA	FA	MA	FA	MA	MA	FA	MA	FA	MA / FA	MA	MA	FA	FA	MA	E				
		4.27	4.42	4.44	4.48	4.44	4.60	4.31	4.95	4.43	4.52	4.78	4.67	5.29	4.74	5.00	4.87	4.88	5.01	5.29				
19181	13/12	FA	FA	MA	FA	MA	FA	FA / FA	FA	FA	FA	MA	MA	FA	MA	MA	MA	FA						
		4.34	4.72	4.72	4.49	4.71	4.63	4.76	4.38	4.38	4.37	4.94	5.03	4.72	5.00	4.77	5.11	4.91						
19182	9/11	MA	FA	FA	FA	FA	MA	FA / FA	FA	FA	FA	MA	FA	MA	FA	MA	FA							
		4.47	4.46	4.19	4.57	4.31	4.40	4.64	4.37	4.03	4.19	4.22	4.54	3.33	4.65	3.91	4.54	4.53						
19184	10/ 9	MA	MA	MA	MA	FA	MA	FA	FA	MA	MA / MA	FA	MA	MA	MA	FA	MA	FA						
		4.77	4.66	4.62	5.05	4.56	5.00	4.25	4.24	4.82	5.16	4.51	4.37	4.95	4.70	4.94	4.62	4.74	5.02					
19185	8/11	MA	MA	FA	MA	MA	MA	FA / FA	FA	FA	MA	MA	MA	FA	MA	MA	FA	FA	MA					
		4.88	4.88	2.45	4.58	4.77	4.00	4.24	4.44	4.36	4.58	4.49	4.28	4.25	4.77	4.67	4.48	4.61	4.57					

M = MALE F = FEMALE A = ALIVE E = EARLY RESORPTION L = LATE RESORPTION "/" DENOTES POSITION OF CERVIX  
CLs = CORPORA LUTEA/OVARY FETAL BODY WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B34 (PAGE 8): FETAL SEX, VITAL STATUS AND BODY WEIGHT - INDIVIDUAL DATA - PART D

DOSAGE GROUP IV		1.0 MG/KG/DAY																						
FETUS #		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
RAT #	CLs																							
19186	9/12	MA	MA	FA	MA	MA	MA	MA / FA	FA	FA	MA	FA	MA	MA	FA	MA	MA							
		4.92	4.90	4.81	4.79	4.89	4.77	4.67	4.42	4.32	4.50	4.87	4.55	4.35	4.46	2.36	4.26	4.37						
19187	9/ 8	FA	MA	FA	FA	MA	MA	MA	MA	FA / MA	MA	MA	FA	MA	FA	FA								
		4.13	4.48	4.14	3.85	4.32	4.49	4.37	4.55	3.96	4.57	4.35	4.66	4.41	4.56	4.37	4.24							
19188	9/10	FA	FA	FA	E	FA	MA	FA	FA / FA	FA	FA	MA	MA	FA	MA	MA	MA							
		3.52	4.16	4.24		4.24	4.17	4.37	4.42	3.78	4.23	4.45	4.23	4.46	4.16	4.52	4.45	4.74						
19189	7/12	MA	FA / MA	MA																				
		4.92	4.85	5.54	5.35																			
19190	11/11	MA	FA	MA	FA	MA	FA	FA	FA	FA	FA	FA / MA	FA	MA	FA	MA	MA	FA	FA	FA	MA	MA		
		4.41	4.47	4.68	4.51	4.42	4.81	4.14	4.33	4.60	4.28	4.33	4.16	4.81	4.76	4.30	4.32	4.57	4.65	4.44	4.54	4.96	4.95	
19191	8/10	MA	FA	FA	MA	FA	FA	FA	MA / FA	FA	MA	MA	FA	MA	FA	MA	MA	MA						
		4.51	4.31	4.52	4.61	4.65	4.37	4.52	4.77	4.45	4.60	4.95	4.69	4.17	4.29	4.30	4.55	4.01	4.77					
19193	9/10	MA	FA	FA	FA	MA	FA	MA	FA / FA	MA	MA	MA	FA	MA	MA									
		5.04	4.48	4.47	4.55	4.66	4.59	4.91	4.26	4.67	4.76	4.69	4.62	4.59	4.76	4.81								
19196	11/11	MA	MA	FA	E	MA	MA	FA / MA	MA	MA	MA	FA	E	FA	FA	MA	FA	MA						
		4.32	4.43	4.28		4.47	4.44	4.67	3.95	4.01	4.45	4.14		4.17	4.06	4.29	4.28	4.74						

M = MALE F = FEMALE A = ALIVE E = EARLY RESORPTION L = LATE RESORPTION "/" DENOTES POSITION OF CERVIX  
 CLS = CORPORA LUTEA/OVARY FETAL BODY WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B34 (PAGE 9): FETAL SEX, VITAL STATUS AND BODY WEIGHT - INDIVIDUAL DATA - PART D

DOSAGE GROUP V				30.0 MG/KG/DAY																				
FETUS #		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
RAT #	CLS																							
19197	10/ 8	FA	FA	E	MA	MA	MA	MA	MA	FA /	FA	FA	FA	FA	MA	MA	MA	FA						
		3.95	4.27		4.55	4.41	3.92	4.79	4.62	4.00	4.23	3.93	4.64	4.51	4.55	4.26	4.48	4.39						
19198	10/ 6	FA	MA	E	MA	MA	MA	FA	MA	MA	E /	MA	FA	FA	E	FA	FA							
		4.40	4.57		4.49	4.85	4.89	4.45	4.87	4.88		4.85	4.42	4.68		4.38	4.63							
19199	15/13	MA	MA	MA	MA	MA	FA	MA	MA /	FA	MA	E	FA	FA	FA	FA								
		3.81	4.16	4.39	4.28	4.47	4.03	4.60	4.44	4.25	4.58		3.77	4.17	4.13	4.15								
19200	11/ 9	E	MA	FA	MA	MA	MA	FA	FA	MA	FA /	FA	FA	MA	E	FA	FA	FA	E					
			3.49	3.36	3.69	3.44	3.12	3.60	3.60	3.24	3.21	3.32	3.27	3.79		3.40	3.44	4.02						
19201	14/ 4	FA	FA	FA	MA	MA	MA	FA	FA	FA	MA	FA	FA	MA /	FA	MA								
		3.77	4.19	3.79	3.98	4.21	4.76	4.16	4.13	3.92	4.38	4.05	4.07	4.49	3.96	4.67								
19202	11/14	MA	MA /	MA	FA	MA	FA	MA	FA	MA	MA													
		4.25	4.21	3.67	3.79	4.16	3.99	4.11	3.79	4.38	4.55													
19204	11/11	MA	FA	FA	FA	FA	FA	MA	MA	MA	FA /	FA	FA	MA	MA	FA	MA	FA	MA	FA	FA	FA	FA	
		4.44	4.26	4.44	4.62	4.53	4.33	4.44	4.68	4.88	4.52	4.16	4.53	4.37	4.31	4.48	4.96	4.42	4.51	4.39	4.38			
19205	13/11	MA	MA	FA	MA	FA	FA	FA	FA	FA /	MA	FA	FA	FA	E	MA	FA							
		4.34	3.95	4.08	4.05	4.32	4.05	4.09	4.24	4.03	4.21	4.01	4.46	4.39		4.51	4.18							
19206	9/ 9	FA	FA	E	FA	MA	MA	FA	MA /	MA	FA	FA	FA	MA	FA	MA								
		3.43	4.14		4.24	3.89	3.71	4.22	4.17	3.77	3.99	3.94	4.04	3.81	4.24	4.12								
19207	7/ 6	MA	MA	FA	MA	FA	MA	FA /	MA	MA	MA	FA	FA	MA										
		4.63	4.62	4.73	4.46	4.61	5.03	5.11	4.78	4.19	5.15	4.55	5.05	5.11										
19208	10/ 9	MA	MA	FA	MA	MA	MA	FA	MA	MA	FA /	MA	MA	FA	FA	MA	FA							
		4.10	4.47	4.01	4.59	4.31	4.34	3.76	4.05	4.18	4.21	4.33	3.94	3.23	4.01	4.70	3.90							
M = MALE    F = FEMALE    A = ALIVE    E = EARLY RESORPTION    L = LATE RESORPTION    "/" DENOTES POSITION OF CERVIX																								
CLS = CORPORA LUTEA/OVARY        FETAL BODY WEIGHTS WERE RECORDED IN GRAMS (G).																								

M = MALE F = FEMALE A = ALIVE E = EARLY RESORPTION L = LATE RESORPTION "/" DENOTES POSITION OF CERVIX  
 CLS = CORPORA LUTEA/OVARY FETAL BODY WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B34 (PAGE 10): FETAL SEX, VITAL STATUS AND BODY WEIGHT - INDIVIDUAL DATA - PART D

DOSAGE GROUP V				30.0 MG/KG/DAY																				
FETUS #		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
RAT #	CLs																							
19210	10/ 6	MA	MA	MA	MA	FA	FA	FA	FA /	MA	MA	FA	FA											
		4.87	5.07	5.15	5.20	5.01	5.14	4.70	4.65	4.10	5.07	4.67	4.64											
19211	9/10	FA	FA	FA	MA	MA	E	MA	FA	MA /	MA	FA	MA	FA	FA	FA	FA	FA						
		4.44	4.32	4.14	4.80	4.44		4.78	4.59	4.47	4.88	4.44	4.66	4.68	4.46	4.18	4.26	4.57						
19212	14/14	MA	MA	FA	FA	MA	FA	FA	FA /	MA	MA	MA	FA	FA	MA	MA	FA	FA	E	FA				
		4.33	4.09	4.15	4.41	4.66	4.23	3.95	4.38	4.17	4.32	4.27	3.79	3.94	4.17	4.38	4.13	4.06			4.33			
19213	10/ 8	MA	MA	FA	E	FA	MA	MA	FA	MA	FA /	FA	MA	MA	MA	E	FA	MA						
		5.28	5.14	4.66		4.43	4.78	4.83	4.89	4.96	4.51	4.53	5.52	5.16	4.81		4.86	5.60						
19215	9/ 4	FA /	E																					
		6.93																						
19216	10/ 8	FA	FA	MA	FA	FA /	MA	FA	FA	FA	FA	FA	MA											
		4.48	4.74	4.87	4.39	4.58	4.71	2.86	4.31	4.68	4.53	4.45	5.00											
19218	12/11	MA	FA	MA	FA	MA	MA	MA	MA	FA /	MA	MA	MA	MA	MA	MA	MA	MA						
		4.52	4.66	5.10	4.59	4.84	4.69	4.99	4.91	4.30	4.80	5.01	4.96	5.07	4.97	4.78	4.85	4.79						
19219	8/11	FA	MA	FA	FA	MA	MA	FA /	MA	FA	FA	MA	FA	MA	MA	MA	MA							
		3.80	4.41	3.57	4.13	4.47	4.32	3.96	4.51	3.98	4.25	4.25	4.08	4.14	4.07	4.35	4.30							
19220	12/10	FA	MA	MA	FA	MA	FA	MA	MA	FA	FA	FA /	FA	MA	FA									
		3.02	4.95	4.49	4.49	4.79	4.18	4.69	4.65	4.30	4.43	4.77	4.58	4.95	4.73									
M = MALE    F = FEMALE    A = ALIVE    E = EARLY RESORPTION    L = LATE RESORPTION    "/" DENOTES POSITION OF CERVIX																								
CLs = CORPORA LUTEA/OVARY        FETAL BODY WEIGHTS WERE RECORDED IN GRAMS (G) .																								

M = MALE F = FEMALE A = ALIVE E = EARLY RESORPTION L = LATE RESORPTION "/" DENOTES POSITION OF CERVIX  
CLs = CORPORA LUTEA/OVARY FETAL BODY WEIGHTS WERE RECORDED IN GRAMS (G).

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B35 (PAGE 1): FETAL ALTERATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP I		0 (CARRIER) MG/KG/DAY					
RAT NUMBER	SPECIMENS WITH ANY ALTERATIONS N(%)	GROSS EXTERNAL EXAMINATION		SOFT TISSUE EXAMINATION		SKELETAL EXAMINATION	
		N/N	DESCRIPTION	N/N	DESCRIPTION	N/N	DESCRIPTION
19101	0( 0.0)	0/19		0/ 9		0/10	
19102	0( 0.0)	0/17		0/ 8		0/ 9	
19103	2( 12.5)	0/16		2/ 8	FETUS 4 VESSELS: UMBILICAL ARTERY DESCENDED TO THE LEFT OF THE URINARY BLADDER  FETUS 16 VESSELS: INNOMINATE ABSENT	0/ 8	
19104	1( 6.7)	0/15		0/ 7		1/ 8	FETUS 15 CERVICAL VERTEBRAE: CERVICAL RIB PRESENT AT 7TH CERVICAL VERTEBRA, left
19105	0( 0.0)	0/17		0/ 8		0/ 9	
19107	0( 0.0)	0/14		0/ 7		0/ 7	
19108	0( 0.0)	0/16		0/ 8		0/ 8	
19109	1( 6.2)	0/16		0/ 8		1/ 8	FETUS 3 CERVICAL VERTEBRAE: CERVICAL RIB PRESENT AT 7TH CERVICAL VERTEBRA, left

N/N = NUMBER OF SPECIMENS WITH ALTERATIONS/NUMBER OF SPECIMENS EXAMINED

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B35 (PAGE 2): FETAL ALTERATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP I		0 (CARRIER) MG/KG/DAY					
RAT NUMBER	SPECIMENS WITH ANY ALTERATIONS N(%)	GROSS EXTERNAL EXAMINATION		SOFT TISSUE EXAMINATION		SKELETAL EXAMINATION	
		N/N	DESCRIPTION	N/N	DESCRIPTION	N/N	DESCRIPTION
19110	0( 0.0)	0/19		0/ 9		0/10	
19111	0( 0.0)	0/16		0/ 8		0/ 8	
19112	1( 5.6)	0/18		0/ 9		1/ 9	FETUS 1 CERVICAL VERTEBRAE: CERVICAL RIB PRESENT AT 7TH CERVICAL VERTEBRA, bilateral
19113	1( 6.2)	0/16		0/ 8		1/ 8	FETUS 3 STERNAL CENTRA: ASYMMETRIC, 1st - 3rd; FUSED, 1st and 2nd
19114	1( 6.7)	0/15		1/ 7	FETUS 12 VESSELS: AORTIC ARCH BIFURCATED, passed both ventral and dorsal to the esophagus; right carotid arose to the right of the right subclavian; right subclavian arose dorsal to the esophagus; left carotid arose ventral to the esophagus; bifurcation rejoined at the level of the ductus arteriosus; right subclavian arose at the level of the ductus arteriosus. INNOMINATE ABSENT	0/ 8	

N/N = NUMBER OF SPECIMENS WITH ALTERATIONS/NUMBER OF SPECIMENS EXAMINED



PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B35 (PAGE 3): FETAL ALTERATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP I		0 (CARRIER) MG/KG/DAY					
RAT NUMBER	SPECIMENS WITH ANY ALTERATIONS N(%)	GROSS EXTERNAL EXAMINATION		SOFT TISSUE EXAMINATION		SKELETAL EXAMINATION	
		N/N	DESCRIPTION	N/N	DESCRIPTION	N/N	DESCRIPTION
19115	1( 5.3)	0/19		0/ 9		1/10	FETUS 19 CERVICAL VERTEBRAE: CERVICAL RIB PRESENT AT 7TH CERVICAL VERTEBRA, left
19116	0( 0.0)	0/16		0/ 8		0/ 8	
19117	0( 0.0)	0/17		0/ 8		0/ 9	
19119	0( 0.0)	0/19		0/ 9		0/10	
19120	NOT PREGNANT						
19123	0( 0.0)	0/15		0/ 7		0/ 8	
19124	0( 0.0)	0/16		0/ 8		0/ 8	

N/N = NUMBER OF SPECIMENS WITH ALTERATIONS/NUMBER OF SPECIMENS EXAMINED

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B35 (PAGE 4): FETAL ALTERATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP II		0.01 MG/KG/DAY					
RAT NUMBER	SPECIMENS WITH ANY ALTERATIONS N(%)	GROSS EXTERNAL EXAMINATION		SOFT TISSUE EXAMINATION		SKELETAL EXAMINATION	
		N/N	DESCRIPTION	N/N	DESCRIPTION	N/N	DESCRIPTION
19125	0( 0.0)	0/16		0/ 8		0/ 8	
19127	NOT PREGNANT						
19128	0( 0.0)	0/19		0/ 9		0/10	
19130	0( 0.0)	0/15		0/ 7		0/ 8	
19131	0( 0.0)	0/12		0/ 6		0/ 6	
19132	0( 0.0)	0/17		0/ 8		0/ 9	
19133	0( 0.0)	0/14		0/ 7		0/ 7	
19134	1( 6.7)	0/15		0/ 7		1/ 8	FETUS 9 CERVICAL VERTEBRAE: CERVICAL RIB PRESENT AT 7TH CERVICAL VERTEBRA, left
19135	1( 6.2)	0/16		1/ 8	FETUS 6 URETER: DISTENDED, right, slight	0/ 8	
19136	0( 0.0)	0/16		0/ 8		0/ 8	
19137	0( 0.0)	0/10	FETUS 7 LATE RESORPTION, autolysis precluded further evaluation.	0/ 5		0/ 5	

N/N = NUMBER OF SPECIMENS WITH ALTERATIONS/NUMBER OF SPECIMENS EXAMINED

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B35 (PAGE 5): FETAL ALTERATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP II		0.01 MG/KG/DAY					
RAT NUMBER	SPECIMENS WITH ANY ALTERATIONS N(%)	GROSS EXTERNAL EXAMINATION		SOFT TISSUE EXAMINATION		SKELETAL EXAMINATION	
		N/N	DESCRIPTION	N/N	DESCRIPTION	N/N	DESCRIPTION
19139	0( 0.0)	0/17		0/ 8		0/ 9	
19140	1( 5.6)	0/18		0/ 9		1/ 9	FETUS 15 CERVICAL VERTEBRAE: CERVICAL RIB PRESENT AT 7TH CERVICAL VERTEBRA, bilateral
19141	0( 0.0)	0/12		0/ 6		0/ 6	
19143	0( 0.0)	0/ 3		0/ 1		0/ 2	
19144	1( 5.9)	1/17	FETUS 9 SNOUT: CLEFT, lateral right; PALATE: CLEFT, unilateral right	0/ 8		1/ 9	FETUS 9 SKULL: MAXILLAE, INCOMPLETELY OSSIFIED, right; PALATE, INCOMPLETELY OSSIFIED, right; STERNAL CENTRA: INCOMPLETELY OSSIFIED, 1st; THORACIC VERTEBRAE: CENTRUM, BIFID, 13th
19145	0( 0.0)	0/15		0/ 7		0/ 8	
19146	0( 0.0)	0/12		0/ 6		0/ 6	
19147	0( 0.0)	0/16		0/ 8		0/ 8	
19148	0( 0.0)	0/11		0/ 5		0/ 6	

N/N = NUMBER OF SPECIMENS WITH ALTERATIONS/NUMBER OF SPECIMENS EXAMINED

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B35 (PAGE 6): FETAL ALTERATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP III		0.1 MG/KG/DAY					
RAT NUMBER	SPECIMENS WITH ANY ALTERATIONS N(%)	GROSS EXTERNAL EXAMINATION		SOFT TISSUE EXAMINATION		SKELETAL EXAMINATION	
		N/N	DESCRIPTION	N/N	DESCRIPTION	N/N	DESCRIPTION
19150	2 ( 11.8)	0/17		1/ 8	FETUS 6 VESSELS: INNOMINATE ABSENT	1/ 9	FETUS 1 STERNAL CENTRA: INCOMPLETELY OSSIFIED, 1st; PELVIS: PUBIS, NOT OSSIFIED, bilateral
19151	1 ( 14.3)	0/ 7		0/ 3		1/ 4	FETUS 7 CERVICAL VERTEBRAE: CERVICAL RIB PRESENT AT 7TH CERVICAL VERTEBRA, left
19152	0 ( 0.0)	0/16		0/ 8		0/ 8	
19153	NOT PREGNANT						
19155	0 ( 0.0)	0/11		0/ 5		0/ 6	
19156	NOT PREGNANT						
19157	0 ( 0.0)	0/13		0/ 6		0/ 7	
19158	0 ( 0.0)	0/18		0/ 9		0/ 9	
19159	0 ( 0.0)	0/16		0/ 8		0/ 8	
19160	1 ( 11.1)	0/ 9		0/ 4		1/ 5	FETUS 3 CERVICAL VERTEBRAE: CERVICAL RIB PRESENT AT 7TH CERVICAL VERTEBRA, right

N/N = NUMBER OF SPECIMENS WITH ALTERATIONS/NUMBER OF SPECIMENS EXAMINED

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B35 (PAGE 7): FETAL ALTERATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP III		0.1 MG/KG/DAY					
RAT NUMBER	SPECIMENS WITH ANY ALTERATIONS N(%)	GROSS EXTERNAL EXAMINATION		SOFT TISSUE EXAMINATION		SKELETAL EXAMINATION	
		N/N	DESCRIPTION	N/N	DESCRIPTION	N/N	DESCRIPTION
19161	1 ( 5.9)	0/17		1/ 8	FETUS 17 VESSELS: INNOMINATE ABSENT	0/ 9	
19162	0 ( 0.0)	0/18		0/ 9		0/ 9	
19164	3 ( 17.6)	0/17		0/ 8		3/ 9	FETUS 3 CERVICAL VERTEBRAE: CERVICAL RIB PRESENT AT 7TH CERVICAL VERTEBRA, left  FETUS 7 PELVIS: ISCHIUM, INCOMPLETELY OSSIFIED, left; PUBIS, INCOMPLETELY OSSIFIED, bilateral  FETUS 11 CERVICAL VERTEBRAE: CERVICAL RIB PRESENT AT 7TH CERVICAL VERTEBRA, left
19165	0 ( 0.0)	0/16		0/ 8		0/ 8	
19166	NOT PREGNANT						
19167	1 ( 5.9)	0/17		1/ 8	FETUS 2 VESSELS: INNOMINATE ABSENT	0/ 9	

N/N = NUMBER OF SPECIMENS WITH ALTERATIONS/NUMBER OF SPECIMENS EXAMINED

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B35 (PAGE 8): FETAL ALTERATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP III		0.1 MG/KG/DAY					
RAT NUMBER	SPECIMENS WITH ANY ALTERATIONS N(%)	GROSS EXTERNAL EXAMINATION		SOFT TISSUE EXAMINATION		SKELETAL EXAMINATION	
		N/N	DESCRIPTION	N/N	DESCRIPTION	N/N	DESCRIPTION
19168	1 ( 9.1)	0/11		0/ 5		1/ 6	FETUS 9 CERVICAL VERTEBRAE: CERVICAL RIB PRESENT AT 7TH CERVICAL VERTEBRA, right
19170	2 ( 13.3)	0/15		0/ 7		2/ 8	FETUS 12 THORACIC VERTEBRAE: CENTRUM, BIFID, 12th  FETUS 16 THORACIC VERTEBRAE: CENTRUM, BIFID, 12th
19171	0 ( 0.0)	0/15		0/ 7		0/ 8	
19172	0 ( 0.0)	0/ 3		0/ 1		0/ 2	

N/N = NUMBER OF SPECIMENS WITH ALTERATIONS/NUMBER OF SPECIMENS EXAMINED

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B35 (PAGE 9): FETAL ALTERATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP IV		1.0 MG/KG/DAY					
RAT NUMBER	SPECIMENS WITH ANY ALTERATIONS N(%)	GROSS EXTERNAL EXAMINATION		SOFT TISSUE EXAMINATION		SKELETAL EXAMINATION	
		N/N	DESCRIPTION	N/N	DESCRIPTION	N/N	DESCRIPTION
19173	2( 10.5)	0/19		0/ 9		2/10	FETUS 11 THORACIC VERTEBRAE: CENTRUM, BIFID, 11th  FETUS 15 THORACIC VERTEBRAE: CENTRUM, BIFID, 11th
19174	0( 0.0)	0/20		0/10		0/10	
19175	1( 5.9)	0/17		0/ 8		1/ 9	FETUS 3 CERVICAL VERTEBRAE: CERVICAL RIB PRESENT AT 7TH CERVICAL VERTEBRA, left
19176	0( 0.0)	0/14		0/ 7		0/ 7	
19177	0( 0.0)	0/12		0/ 6		0/ 6	
19178	0( 0.0)	0/15		0/ 7		0/ 8	
19179	0( 0.0)	0/16		0/ 8		0/ 8	
19180	0( 0.0)	0/19		0/ 9		0/10	
19181	0( 0.0)	0/17		0/ 8		0/ 9	
19182	0( 0.0)	0/17		0/ 8		0/ 9	
19184	0( 0.0)	0/18		0/ 9		0/ 9	
19185	0( 0.0)	0/18		0/ 9		0/ 9	

N/N = NUMBER OF SPECIMENS WITH ALTERATIONS/NUMBER OF SPECIMENS EXAMINED

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B35 (PAGE 10): FETAL ALTERATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP IV		1.0 MG/KG/DAY					
RAT NUMBER	SPECIMENS WITH ANY ALTERATIONS N(%)	GROSS EXTERNAL EXAMINATION		SOFT TISSUE EXAMINATION		SKELETAL EXAMINATION	
		N/N	DESCRIPTION	N/N	DESCRIPTION	N/N	DESCRIPTION
19186	0( 0.0)	0/17		0/ 8		0/ 9	
19187	1( 6.2)	0/16		1/ 8	FETUS 14 VESSELS: INNOMINATE ABSENT	0/ 8	
19188	0( 0.0)	0/16		0/ 8		0/ 8	
19189	0( 0.0)	0/ 4		0/ 2		0/ 2	
19190	0( 0.0)	0/22		0/11		0/11	
19191	0( 0.0)	0/18		0/ 9		0/ 9	
19193	0( 0.0)	0/15		0/ 7		0/ 8	
19196	1( 6.7)	0/15		0/ 7		1/ 8	FETUS 13 THORACIC VERTEBRAE: CENTRUM, BIFID, 11th

N/N = NUMBER OF SPECIMENS WITH ALTERATIONS/NUMBER OF SPECIMENS EXAMINED



PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B35 (PAGE 11): FETAL ALTERATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP V		30.0 MG/KG/DAY					
RAT NUMBER	SPECIMENS WITH ANY ALTERATIONS N(%)	GROSS EXTERNAL EXAMINATION		SOFT TISSUE EXAMINATION		SKELETAL EXAMINATION	
		N/N	DESCRIPTION	N/N	DESCRIPTION	N/N	DESCRIPTION
19197	0( 0.0)	0/16		0/ 8		0/ 8	
19198	1( 7.7)	0/13		0/ 6		1/ 7	FETUS 11 CERVICAL VERTEBRAE: CERVICAL RIB PRESENT AT 7TH CERVICAL VERTEBRA, right
19199	0( 0.0)	0/14		0/ 7		0/ 7	
19200	0( 0.0)	0/15		0/ 7		0/ 8	
19201	0( 0.0)	0/15		0/ 7		0/ 8	
19202	1( 10.0)	0/10		0/ 5		1/ 5	FETUS 7 PELVIS: PUBIS, NOT OSSIFIED, bilateral
19204	0( 0.0)	0/20		0/10		0/10	
19205	0( 0.0)	0/15		0/ 7		0/ 8	
19206	1( 7.1)	0/14		0/ 7		1/ 7	FETUS 8 STERNAL CENTRA: INCOMPLETELY OSSIFIED, 1st
19207	0( 0.0)	0/13		0/ 6		0/ 7	

N/N = NUMBER OF SPECIMENS WITH ALTERATIONS/NUMBER OF SPECIMENS EXAMINED

PROTOCOL 1416-003: ORAL (DRINKING WATER) DEVELOPMENTAL TOXICITY STUDY OF AMMONIUM PERCHLORATE IN RATS

TABLE B35 (PAGE 12): FETAL ALTERATIONS - INDIVIDUAL DATA - PART D

DOSAGE GROUP V		30.0 MG/KG/DAY					
RAT NUMBER	SPECIMENS WITH ANY ALTERATIONS N(%)	GROSS EXTERNAL EXAMINATION		SOFT TISSUE EXAMINATION		SKELETAL EXAMINATION	
		N/N	DESCRIPTION	N/N	DESCRIPTION	N/N	DESCRIPTION
19208	2( 12.5)	0/16		0/ 8		2/ 8	FETUS 5 RIBS: WAVY, right 6th - 9th and 12th left 12th; INCOMPLETELY OSSIFIED (HYPOPLASTIC), right 9th and 10th  FETUS 15 RIBS: WAVY, right 6th - 12th
19210	0( 0.0)	0/12		0/ 6		0/ 6	
19211	0( 0.0)	0/16		0/ 8		0/ 8	
19212	0( 0.0)	0/18		0/ 9		0/ 9	
19213	0( 0.0)	0/15		0/ 7		0/ 8	
19215	0( 0.0)	0/ 1		0/ 0		0/ 1	
19216	0( 0.0)	0/12		0/ 6		0/ 6	
19218	0( 0.0)	0/17		0/ 8		0/ 9	
19219	0( 0.0)	0/16		0/ 8		0/ 8	
19220	0( 0.0)	0/14		0/ 7		0/ 7	

N/N = NUMBER OF SPECIMENS WITH ALTERATIONS/NUMBER OF SPECIMENS EXAMINED

APPENDIX C  
PROTOCOL AND AMENDMENTS



Argus Research Laboratories, Inc.  
905 Sheehy Drive, Building A  
Horsham, PA 19044  
Telephone: (215) 443-8710  
Telefax: (215) 443-8587

# **PROTOCOL 1416-003**

**STUDY TITLE:** Hormone, Thyroid and Neurohistological Effects of Oral (Drinking Water) Exposure to Ammonium Perchlorate in Pregnant and Lactating Rats and in Fetuses and Nursing Pups Exposed to Ammonium Perchlorate During Gestation or via Maternal Milk

**PURPOSE:** The purposes of this study are: 1) to determine the teratogenicity of perchlorate in a second species (rat); 2) to measure thyroid stimulating hormone (TSH), thyroxine ( $T_4$ ) and triiodothyronine ( $T_3$ ) changes in developing rats (fetal and neonate) and in adult female rats during pregnancy and lactation; 3) to measure neurohistological and thyroid effects at the same time points; and 4) to correlate these effects with hormone concentration changes at different stages in development of the rat.

Data from this study will be used in developing the final Reference Dose (RfD) for perchlorate, needed by the U.S. Environmental Protection Agency for risk assessment and to establish cleanup levels of perchlorate-contaminated sites.

Physiologically based pharmacokinetic (PBPK) models predict tissue dosimetry in the target species and are used to extrapolate animal data to the human for development of exposure standards. This study will provide data for the development of a physiologically based pharmacodynamic (PBD) model to predict TSH,  $T_4$  and  $T_3$  levels in the thyroid gland of fetal, neonatal, nonpregnant, pregnant and lactating rats. The resulting PBPK and PBD models, combined with a PBPK model for perchlorate iodine inhibition kinetics generated from data in a parallel study, will provide scientific basis for the health risk posed by low level human exposure, including potential sensitive sub-populations, to perchlorate in drinking water.

In order to facilitate study management and expedite sample shipment, the study will be divided into the following four segments:

Part A, during which blood and thyroid samples will be collected from maternal rats and blood, thyroid and brain samples will be collected from fetuses at Caesarean-sectioning on day 21 of presumed gestation;

Part B, during which blood and thyroid samples will be collected from maternal rats on day 10 postpartum and blood, thyroid and brain samples will be collected from pups on days 5 and 10 postpartum;

Part C, during which blood and thyroid samples will be collected from maternal rats on day 22 postpartum, and blood, thyroid and brain samples will be collected from pups on day 5 postpartum (culled pups) and on day 22 postpartum.

Part D, during which standard prenatal developmental toxicity endpoints in maternal rats and fetuses will be evaluated (OPPTS 870.3700).

**TESTING FACILITY:**

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905 Sheehy Drive, Building A  
Horsham, Pennsylvania 19044-1297  
Telephone: (215) 443-8710  
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Telefax: (513) 542-7487  
E-Mail: [dourson@tera.org](mailto:dourson@tera.org)

**REGULATORY CITATIONS:**

U.S. Environmental Protection Agency (1998). Office of Prevention, Pesticides and Toxic Substances (OPPTS). *Health Effects Test Guidelines*. OPPTS 870.3700: Prenatal developmental toxicity study. August, 1998.

U.S. Environmental Protection Agency (1998). Office of Prevention, Pesticides and Toxic Substances (OPPTS). *Health Effects Test Guidelines*. OPPTS 870.3800: Reproduction and fertility effects. August, 1998.

U.S. Environmental Protection Agency. Toxic Substances Control Act (TSCA); Good Laboratory Practice Standards; Final Rule. 40 CFR Part 792.

**REGULATORY COMPLIANCE:**

This study will be conducted in compliance with the Good Laboratory Practice (GLP) regulations cited above.

All changes or revisions of this protocol shall be documented, signed by the Study Director and the Sponsor, dated and maintained with the protocol.

The Testing Facility's Quality Assurance Unit (QAU) will audit the protocol, the raw data and the report, and will inspect critical phases of those portions of the study conducted at the Testing Facility in accordance with the Standard Operating Procedures of Argus Research Laboratories, Inc.

Should any portion of the study be conducted by a subcontractor or by the Sponsor, the QAU for that facility will conduct critical phase inspections and audit respective results and reports for that study portion according to the SOPs of that facility. Such critical phase inspection reports and report audits will be submitted by that facility to the Study Director. The dates of the inspections and report submissions will be incorporated into a QAU Statement generated by that facility and provided to the Testing Facility for inclusion in the final report.

The final report will include a compliance statement signed by the Study Director that the report accurately reflects the raw data obtained during the performance of the study and that all applicable GLP regulations were followed in the conduct of the study.

Should significant deviations from GLP regulations occur, each will be described in detail, together with how the deviation might affect the quality or integrity of the study.

**SCHEMATIC OF STUDY DESIGN AND STUDY SCHEDULE:**

See ATTACHMENT 1 to the protocol.

**TEST SUBSTANCE AND CARRIER:**

**Identification:**

**Test Substance:**

Ammonium Perchlorate (CAS Number 7790-98-9). Source and lot identification will be added to the protocol prior to finalization or documented by amendment.

**Carrier:**

Reverse osmosis membrane processed deionized water (R.O. deionized water). Results of R.O. deionized water analyses will be included in the raw data and the final report.

Neither the Sponsor nor the Study Director is aware of any potential contaminants likely to be present in the carrier that would interfere with the results of this study. Therefore, no analyses other than those mentioned in this protocol will be conducted.

**Safety Precautions:**

Gloves, mask, appropriate eye protection to be worn during formulation preparation. The Material Safety Data Sheet (MSDS) is attached to the protocol (ATTACHMENT 2).

**Storage:**

Bulk Test Substance:	Room temperature.
Carrier:	Room temperature.
Prepared Formulations:	The prepared stock formulation will be stored refrigerated. Dosage solutions will be stored at room temperature.

The test substance will be provided by the Testing Facility.

**FORMULATION:****Frequency of Preparation:**

Formulations of the test substance will be prepared at least once weekly at the Testing Facility.

Detailed preparation procedures will be attached to this protocol (ATTACHMENT 3).

**Adjustment for Purity:**

The test substance will be considered 100% pure for the purpose of dosage calculations.

**Testing Facility Reserve Samples:**

The Testing Facility will reserve a sample (5 g) of each lot of bulk test substance and a sample (5 mL) of the carrier used during the course of the study. Samples will be stored under the previously cited conditions. A reserve sample (1 g) of each lot of the test substance will be taken on the last day of exposure and stored at the Testing Facility under previously cited conditions.

**ANALYSES:**

Samples additional to those described below may be taken if deemed necessary during the course of the study.

**Stability of Prepared Solutions:**

Documentation of the stability of the prepared solutions, at concentrations that bracket the range to be used in this study, is on file with the Sponsor. Stability has been established for up to 109 days.

**Concentration Analyses:**

Concentration of the test substance in prepared solutions will be verified during the course of this study. Triplicate samples (2 mL each) will be taken from each formulation (including stock solution and carrier) on the first and last days of preparations. Two samples from each triplicate set will be shipped for analysis; the remaining samples will be retained at the Testing Facility as backup samples. Backup samples will be stored under the previously cited conditions and discarded at the Testing Facility following report finalization.



**Shipping Instructions:**

Samples to be analyzed will be shipped (refrigerated on cold packs) to:

David Mattie, Ph.D., DABT  
 Director of Program Development  
 Operational Toxicology Branch  
 Air Force Research Laboratory (AFRL)  
 AFRL/HEST Building 79  
 2856 G Street  
 Wright Patterson Air Force Base, Ohio 45433-7400  
 Telephone: (937) 255-5150, X3105  
 Telefax: (937) 255-1474  
 E-Mail: [mattie@falcon.al.wpafb.af.mil](mailto:mattie@falcon.al.wpafb.af.mil)

The recipient will be notified in advance of sample shipment.

**DISPOSITION:**

All remaining, unused bulk test substance and prepared formulations will be discarded at the Testing Facility.

**TEST SYSTEM:****Species/Strain and Reason for Selection:**

The CrI:CD®(SD)IGS BR VAF/Plus® rat was selected as the Test System because: 1) this strain of rat has been demonstrated to be sensitive to reproductive and developmental toxins and has been widely used throughout industry for reproductive and developmental toxicity evaluations; and 2) historical data and experience exist at the Testing Facility<sup>(1-3)</sup>.

**Number:**

Initial population acclimated	500 virgin female rats.
Population selected for assignment to exposure groups	460 virgin female rats (23 rats per group per study segment).
Population selected for continuation on study through completion of Caesarean-section or natural delivery observations	340 mated female rats (16 rats per group per study PARTS A, B and C, and 20 rats per group for study PART D.)

**Body Weight and Age:**

Female rats will be ordered to have body weights of 200 g to 225 g each at receipt, at which time they will be expected to be at least 60 days of age. Actual body weights will be recorded the day after receipt and will be documented in the raw data. The weight range will be included in the final report.

**Sex:**

Female rats will be given the test substance. Male rats of the same source and strain will be used only as breeders and are not considered part of the Test System. (Note: Breeder male rats will be exposed to the test substance during the cohabitation period, and will be sacrificed upon completion of the cohabitation period.)

**Source:**

Charles River Laboratories, Inc.

The rats will be shipped in filtered cartons by air freight and/or truck from Charles River Laboratories, Inc., to the Testing Facility.

**Identification:****P Generation:**

Rats are permanently identified using Monel® self-piercing ear tags (Gey Band and Tag Co., Inc., No. MSPT 20101). Male rats are given unique permanent identification numbers upon assignment to the Testing Facility's breeder male rat population. Female rats are assigned temporary numbers at receipt and given unique permanent identification numbers when assigned to the study on the basis of day 0 of presumed gestation body weights.

**F1 Generation:**

Pups will not be individually identified during lactation; all parameters will be evaluated in terms of the litter.

**ANIMAL HUSBANDRY:**

All cage sizes and housing conditions are in compliance with the *Guide for the Care and Use of Laboratory Animals*<sup>(4)</sup>.

**Housing:****P Generation Rats/F1 Generation Litters:**

P generation rats will be individually housed in stainless steel wire-bottomed cages except during the cohabitation and postpartum periods. During cohabitation, each pair of rats will be housed in the male rat's cage. Beginning no later than day 20 of presumed gestation, P generation female rats assigned to natural delivery will be individually housed in nesting boxes. Each dam and delivered litter will be housed in a common nesting box during the postpartum period.

**Nesting Material:**

Nesting material (bed-o-cobs®) will be provided.

Bedding will be changed as often as necessary to keep the animals dry and clean. Analyses for possible contamination are conducted annually and documented in the raw data.

**Room Air, Temperature and Humidity:**

The animal room is independently supplied with at least ten changes per hour of 100% fresh air that has been passed through 99.97% HEPA filters. Room temperature will be maintained at 64°F to 79°F (18°C to 26°C) and monitored constantly. Room humidity will also be monitored constantly and maintained at 30% to 70%.

**Light:**

An automatically controlled 12-hour light:12-hour dark fluorescent light cycle will be maintained. Each dark period will begin at 1900 hours EST.

**Diet:**

Rats will be given Certified Rodent Diet® #5002 (PMI Nutrition International) available *ad libitum* from individual feeders.

**Water:**

All water will be from a local source and passed through a reverse osmosis membrane before use (R.O. deionized water). Water is analyzed monthly for possible bacterial contamination and twice annually for possible chemical contamination.

During the acclimation period, rats will be given R.O. deionized water only, available *ad libitum* from individual amber bottles attached to the cages. Chlorine will not be added to the R.O. deionized water during the acclimation period.

During the exposure period, rats will be given either R.O. deionized water only (carrier control group) or water prepared using R.O. deionized water and the test substance, available *ad libitum* from individual amber bottles attached to the cages.

**Contaminants:**

Neither the Sponsor nor the Study Director is aware of any potential contaminants likely to be present in the certified diet, the drinking water or the nesting material at levels that would interfere with the results of this study. Therefore, no analyses other than those routinely performed by the feed supplier or those mentioned in this protocol will be conducted.

**RANDOMIZATION AND COHABITATION:**

Upon arrival, male and female rats will be assigned to individual housing on the basis of computer-generated random units. After acclimation, rats will be selected for study on the basis of physical appearance and body weight. The rats will be assigned to groups based on computer-generated (weight-ordered) randomization procedures.

Following two weeks of exposure to the test substance, the female rats will be cohabited with breeder male rats, one male rat per female rat. The cohabitation period will consist of a maximum of five days. Female rats with spermatozoa observed in a smear of the vaginal contents and/or a copulatory plug observed *in situ* will be considered to be at day 0 of presumed gestation and assigned to individual housing.

Sixteen female rats per group per study segments A, B and C will be selected either at the time of Caesarean-sectioning or upon completion of appropriate sample collections for rats assigned to natural delivery. Twenty female rats per group for study segment D will be selected for Caesarean-sectioning. After evaluations have been completed for the appropriate number of rats per group per segment, the remaining rats in that group will be sacrificed and discarded without further evaluation.

Day 1 of lactation (postpartum) is defined as the day of birth and is also the first day on which all pups in a litter are individually weighed (pup body weights will be recorded after all pups in a litter are delivered and groomed by the dam).

Randomization procedures specific to study segments (A, B, C or D) are discussed below.

**Part A:**

The thyroid and brain from one male fetus from each odd-numbered litter and from one female fetus from each even-numbered litter will be selected for histopathological and morphometric evaluation. Thyroid, brain and blood samples will be collected from all remaining fetuses. The timing of these collection processes will be staggered across exposure groups.

**Part B:**

On day 5 postpartum, four pups per sex per litter will be randomly selected for continuation on study until day 10 postpartum. The timing of this process will be staggered across exposure groups. The remaining pups will be sacrificed for blood, thyroid and brain tissue collection on day 5 postpartum.

The thyroid and brain from one male pup from each odd-numbered litter and from one female pup from each even-numbered litter will be selected for histopathological and morphometric evaluation. One set of male and female pups will be selected for evaluation from those pups sacrificed on day 5 postpartum; a second set will be selected for evaluation from those pups sacrificed on day 10 postpartum. The timing of these collection processes will be staggered across exposure groups.

**Part C:**

On day 5 postpartum, four pups per sex per litter will be randomly selected for continuation on study until day 22 postpartum. The timing of this process will be staggered across exposure groups. Pups culled on day 5 postpartum will be sacrificed and retained in neutral buffered 10% formalin without further analysis.

Pups continued on study will be sacrificed on day 22 postpartum. From among these pups, the thyroid and brain from one male pup from each odd-numbered litter and from one female pup from each even-numbered litter will be selected for histopathological and morphometric evaluation. The timing of these processes will be staggered across exposure groups.

**ADMINISTRATION:****Route and Reason for Choice:**

The oral (drinking water) route was selected because it is the most likely route of human exposure.

**Method and Frequency:**

A constant concentration (%) of the test substance equivalent to the target dosages specified in the table below will be offered to the rats in the drinking water. The actual dosages consumed (mg/kg/day) will be calculated and presented for periods corresponding to body weight and water consumption observations. Concentrations will be adjusted weekly as necessary, based on actual body weight and water consumption values recorded the previous week.

**P Generation Rats:**

Rats will be given continual access to the test substance in the drinking water beginning 14 days before cohabitation and continuing through the day before sacrifice. During the cohabitation period, male rats will have access to the water bottles of the female rats.

**F1 Generation:**

F1 generation rats will not be directly given the test substance but may be exposed *in utero* during gestation and via maternal milk and maternal water during the postpartum period.

**Rationale for Dosage Selection and Frequency :**

Target dosage levels were selected by the Sponsor based on previous studies conducted with the test substance. The 10 mg/kg/day dosage resulted in thyroid effects in pups on day 5 postpartum (DP 5) in a neurobehavioral developmental study (Argus Research Laboratories, Inc., Protocol 1613-002), and was clearly an effect level in a 90-day drinking water study in rats<sup>(5)</sup>.

Because the dosage in the neurobehavioral developmental study did not begin until after mating (confirmation of pregnancy), exposure will start two weeks prior to the start of cohabitation to ensure a hypothyroid state, and will continue until sacrifice.

**Target Dosage Levels, Concentrations and Volumes:**

Dosage Group	Target Dosage (mg/kg/day)	Concentration (µg/mL) <sup>a</sup>	Argus Batch Number
I	0 (Carrier)	0	B-1416-003-A(Day.Month.Year)
II	0.01	0.08	B-1416-003-B(Day.Month.Year)
III	0.1	0.8	B-1416-003-C(Day.Month.Year)
IV	1.0	7.6	B-1416-003-D(Day.Month.Year)
V	30.0	227.4	B-1416-003-E(Day.Month.Year)

The test substance will be considered 100% pure for the purpose of dosage calculations.

- a. Based on average water consumption of 33 mL per rat per day (132 mL per kg per day) for a 250 g rat. These concentration levels will be adjusted weekly based on actual body weight and water consumption values recorded the previous week.

**TESTS, ANALYSES AND MEASUREMENTS - P GENERATION:****Viability:**

All Periods: At least twice daily.

**Clinical Observations and/or General Appearance:**

Pre-exposure Period: At least once.

Exposure Period: Daily.

Maternal Behavior: Days 1, 5, 8 and 10 postpartum (rats assigned to study segment B) or days 1, 5, 8, 14 and 22 postpartum (rats assigned to study segment C).  
Observed abnormal behavior recorded daily.

Clinical observations may be recorded more frequently than cited above, if deemed appropriate by the Study Director and/or Study Monitor.

**Body Weights:**

Pre-exposure Period: At least once.

Exposure Period: Daily.

Sacrifice: Terminal weight.

**Feed Consumption Values:**

Exposure Period: Daily.

Feed consumption will not be tabulated for female rats without confirmed mating dates during the cohabitation period. Feed consumption will not be tabulated after day 14 postpartum, when it is expected that pups will begin to consume maternal feed.

**Water Consumption Values:**

Exposure Period: Daily.

Water consumption will not be tabulated for female rats without confirmed mating dates during the cohabitation period. Water consumption will not be tabulated after day 14 postpartum, when it is expected that pups will begin to consume maternal water.

**Mating Performance:**

Mating will be evaluated daily during the cohabitation period and confirmed by observation of spermatozoa in a smear of the vaginal contents and/or a copulatory plug observed *in situ*.

**Caesarean-Sectioning Observations - Parts A and D:**

Rats assigned to study segments A and D will be Caesarean-sectioned on day 21 of presumed gestation. Details of maternal blood and tissue sample collection are discussed below. The gravid uterus will be excised and weighed for rats assigned to study segment D. The fetuses will be removed from the uterus and placed in individual containers. The rats will be examined for number and distribution of:

Corpora Lutea.

Implantation Sites [Placentae that appear abnormal (size, color or shape) will be noted in the raw data.]

Live and Dead Fetuses.

(A live fetus is defined as one that responds to stimuli; a dead fetus is defined as a term fetus that does not respond to stimuli and that is not markedly autolyzed; dead fetuses demonstrating marked to extreme autolysis are considered to be late resorptions.)

Early and Late Resorptions.

(A conceptus is defined as a late resorption if it is grossly evident that organogenesis has occurred; if this is not the case, the conceptus is defined as an early resorption.)



**Fetal Observations - Part A:****Gender, Body Weights and Identification:**

Fetuses will be examined for sex. Late resorptions and dead fetuses also will be examined for sex to the extent possible but such observations will not be included in either data summarization or statistical analyses.

The body weight of each fetus will be recorded. Only body weights of live fetuses will be used to determine litter fetal body weight averages.

All fetuses will be fixed for at least forty-eight hours in Bouin's solution and retained in neutral buffered 10% formalin. One male fetus from each odd-numbered litter and one female fetus from each even-numbered litter will be selected for histological and morphometrical evaluation of the brain and thyroid. Details of these evaluations are described below.

**Blood Sample Collection:**

Blood samples for evaluation of thyroid hormones will be collected from the fetuses not selected for histological evaluation. Samples will be collected following decapitation immediately after sacrifice and pooled per litter. Blood will be collected into serum separator tubes to yield approximately 1125  $\mu$ L of serum, to be aliquotted into three vials of approximately 500, 500 and 125  $\mu$ L for TSH, T<sub>3</sub> and T<sub>4</sub> determination, respectively. Serum samples will be immediately frozen on dry ice and maintained frozen (-70°C) until shipment for analysis.

**Shipment of Serum Samples:**

After completion of sample collection, samples will be shipped (frozen on dry ice) to:

David Mattie, Ph.D., DABT  
Director of Program Development  
Operational Toxicology Branch  
Air Force Research Laboratory (AFRL)  
AFRL/HEST Building 79  
2856 G Street  
Wright Patterson Air Force Base, Ohio 45433-7400  
Telephone: (937) 255-5150, X3105  
Telefax: (937) 255-1474  
E-Mail: [mattie@falcon.af.mil](mailto:mattie@falcon.af.mil)

The recipient will be notified in advance of sample shipment.

**Fetal Observations - Part D:****Gross External Alterations and Sex:**

Fetuses will be examined for sex and for gross external alterations. Late resorptions and dead fetuses also will be examined for sex and for gross external alterations to the extent possible but such observations will not be included in either data summarization or statistical analyses.

**Body Weights and Identification:**

The body weight of each fetus will be recorded. Only body weights of live fetuses will be used to determine litter fetal body weight averages. Fetuses will be tagged with identification noting study number, litter number, uterine distribution and fixative.

**Soft Tissue Examination:**

Approximately one-half of the fetuses in each litter will be examined for soft tissue alterations by using a variation of the microdissection technique of Staples<sup>(6)</sup>. The heads of these fetuses will be fixed in Bouin's solution and subsequently examined by free-hand sectioning; head sections will be stored in alcohol. The decapitated carcasses will be processed to be retained in glycerin with thymol added as a preservative.

**Skeletal Examination:**

The remaining fetuses (approximately one-half of the fetuses in each litter) will be examined for skeletal alterations and cartilage development after staining with alizarin red S<sup>(7)</sup>. The fetuses will be initially fixed in alcohol; skeletal preparations will be retained in glycerin with thymol added as a preservative.

Representative photographs of fetal gross, soft tissue and skeletal alterations will be taken.

**METHOD OF SACRIFICE:**

Rats will be sacrificed by carbon dioxide asphyxiation. For Part A of the study, one male or one female fetus per litter will be sacrificed by an intraperitoneal injection of Beuthanasia®-D Special for thyroid collection and the remaining fetuses in each litter will be sacrificed by decapitation for blood collection. For Part D of the study, live fetuses will be sacrificed by an intraperitoneal injection of Beuthanasia®-D Special, manufactured by Schering-Plough Animal Health. Pups from Parts B and C of the study will be sacrificed by carbon dioxide asphyxiation followed by exsanguination.

**NECROPSY:**

Prior to sacrifice, every effort will be made to avoid inducing stress that could affect scheduled hormone evaluations. Because of the circadian rhythm of thyroid hormones, rats will be sacrificed in the morning hours. Sacrifice will be staggered across dosage groups.

Gross lesions will be retained in neutral buffered 10% formalin for possible future evaluation. Unless specifically cited below, all other tissues will be discarded.

**Maternal Blood and Tissue Sample Collection - Study Segments A, B and C:**

Blood samples for evaluation of thyroid hormones will be collected from the inferior vena cava immediately following sacrifice. The time of sample collection will be documented in the raw data. Blood will be collected into serum separator tubes to yield approximately 1125 µL of serum, to be aliquotted into three vials of approximately 500, 500 and 125 µL for TSH, T<sub>3</sub> and T<sub>4</sub> determination, respectively. Serum samples will be immediately frozen on dry ice and maintained frozen (-70°C) until shipment for analysis.

The thyroids and parathyroids and a section of the trachea of all maternal rats will be excised and immersed in fixative immediately after collection, following procedures described in ATTACHMENT 4. Following fixation, the thyroid/parathyroid tissue samples will be carefully trimmed and weighed. When possible, the same technician will perform all trimming of thyroid/parathyroid tissues at least 48 hours postfixation. Postfixation organ weights will be recorded. Thyroid tissues will be evaluated histologically. Details of these evaluations are discussed in ATTACHMENT 5.

**Shipment of Maternal Serum Samples:**

After completion of sample collection for each study segment, samples will be shipped (frozen on dry ice) to:

David Mattie, Ph.D., DABT  
Director of Program Development  
Operational Toxicology Branch  
Air Force Research Laboratory (AFRL)  
AFRL/HEST Building 79  
2856 G Street  
Wright Patterson Air Force Base, Ohio 45433-7400  
Telephone: (937) 255-5150, X3105  
Telefax: (937) 255-1474

The recipient will be notified in advance of sample shipment.

**Shipment of Maternal Thyroid Tissue Samples:**

Tissue samples will be shipped for histological evaluation to:

Kathleen Funk, D.V.M., Ph. D.  
Experimental Pathology Laboratories, Inc.  
222866 Shaw Road  
Sterling, Virginia 20166  
Telephone: (703) 471-7060 Ext. 206  
Telefax: (703) 471-8447  
E-Mail: kfunk@epl-inc.com

The recipient will be notified in advance of sample shipment.

**Scheduled Sacrifice - Breeder Male Rats:**

During the course of this study, male rats will be used only as breeders and are not considered part of the Test System. However, these breeder male rats will be exposed to the test substance during the cohabitation period, and will therefore be sacrificed and discarded without further evaluation upon completion of cohabitation.

**Scheduled Sacrifice - Rats Assigned to Caesarean-Sectioning (Parts A and D):**

On day 21 of presumed gestation, female rats will be sacrificed, blood and tissue samples will be collected as described above for rats assigned to study segment A, and a gross necropsy of the thoracic, abdominal and pelvic viscera will be performed. Gravid uterine weights will be recorded for rats assigned to study segment D. Uteri of apparently nonpregnant rats will be examined while being pressed between glass plates to confirm the absence of implantation sites.

**Scheduled Sacrifice - Parts B and C:**

Rats that deliver a litter will be sacrificed on either day 10 (Part B) or day 22 (Part C) postpartum, blood and tissue samples will be collected as described above, and a gross necropsy of the thoracic, abdominal and pelvic viscera will be performed; the number and distribution of implantation sites will be recorded.

**Dams with No Surviving Pups - Parts B and C:**

Dams with no surviving pups will be sacrificed after the last pup is found dead, missing or presumed cannibalized. A gross necropsy of the thoracic, abdominal and pelvic viscera will be performed. Thyroid/parathyroid tissues will be excised and retained as described above and in ATTACHMENT 4.

**Scheduled Sacrifice - Rats Not Selected for Continuation on Study:**

P generation rats not among the sixteen or twenty per group per study segment selected upon Caesarean-sectioning or completion of sample collection will be sacrificed and discarded without further evaluation.

**Rats Found Dead or Moribund:**

Rats that die or are sacrificed because of moribund condition, abortion or premature delivery will be examined for the cause of death or moribund condition on the day the observation is made. The rats will be examined for gross lesions. Pregnancy status and uterine contents of female rats will be recorded. Aborted fetuses, delivered pups and/or conceptuses *in utero* will be examined to the extent possible, using the same methods described for term fetuses. Uteri of apparently nonpregnant rats will be examined while being pressed between glass plates to confirm the absence of implantation sites. Thyroid/parathyroid tissues will be excised and retained as described above and in ATTACHMENT 4. Gravid uteruses will be saved in 10% buffer formalin.

**TESTS, ANALYSES AND MEASUREMENTS - F1 GENERATION (STUDY SEGMENTS B AND C):****Viability:**

Prewaning Period: Litters will be observed for dead pups at least twice daily. The pups in each litter will be counted once daily.

**Clinical Observations and/or General Appearance:**

Prewaning Period: Once daily.

Clinical observations may be recorded more frequently than cited above, if deemed appropriate by the Study Director and/or the Study Monitor.

**Body Weights:**

Prewaning Period: Days 1 (birth), 5, 8 and 10 postpartum (Part B) or days 1, 5, 8, 14 and 22 postpartum (Part C).

Sacrifice: Terminal weight.

**METHOD OF SACRIFICE - F1 GENERATION:**

As previously cited for P generation rats.

**NECROPSY - F1 GENERATION:**

Prior to sacrifice, every effort will be made to avoid inducing stress that could affect scheduled hormone evaluations. Pups will be sacrificed in the morning hours, because of the circadian rhythm of thyroid hormones. Sacrifice will be staggered across dosage groups.

Gross lesions will be retained in neutral buffered 10% formalin for possible future evaluation. Unless specifically cited below, all other tissues will be discarded.

**Neonatal Blood and Tissue Sample Collection - Parts B and C:**

Blood samples for evaluation of thyroid hormones will be collected from the inferior vena cava immediately following sacrifice. The time of sample collection will be documented in the raw data. Samples collected from all pups sacrificed on day 5 and day 10 postpartum, including culled pups from both Parts B and C of the study, will be pooled by litter; samples collected from pups sacrificed on day 22 postpartum will be pooled by sex by litter. Blood will be collected into serum separator tubes to yield approximately 1125  $\mu$ L of serum, to be aliquotted into three vials of approximately 500, 500 and 125  $\mu$ L for TSH,  $T_3$  and  $T_4$  determination, respectively. If necessary, sample collection will be prioritized by hormone as follows: TSH, followed by  $T_3$ , followed by  $T_4$ . Serum samples will be immediately frozen on dry ice and maintained frozen ( $-70^{\circ}\text{C}$ ) until shipment for analysis.

All pups will be retained in neutral buffered 10% formalin. The thyroid and brain from one male pup from each odd-numbered litter and from one female pup from each even-numbered litter will be selected for histopathological and morphometric evaluation. One set of male and female pups will be selected for evaluation from those pups sacrificed on day 5 postpartum (Part B); a second set will be selected for evaluation from those pups sacrificed on day 10 postpartum (Part B); and a third set will be selected for evaluation from those pups sacrificed on day 22 postpartum (Part C). Brain and thyroid weights will be recorded postfixation. Details of the histopathological and morphometric analyses are described in ATTACHMENT 5. Pups not selected for these evaluations will be retained in neutral buffered 10% formalin for possible future evaluation. (Note: Pups culled on day 5 postpartum from Part C of the study will be retained in neutral buffered 10% formalin without further evaluation.)

Shipment of Neonatal Serum Samples:

After completion of sample collection for each study segment, samples will be shipped (frozen on dry ice) to:

David Mattie, Ph.D., DABT  
Director of Program Development  
Operational Toxicology Branch  
Air Force Research Laboratory (AFRL)  
AFRL/HEST Building 79  
2856 G Street  
Wright Patterson Air Force Base, Ohio 45433-7400  
Telephone: (937) 255-5150, Ext. 3105  
Telefax: (937) 255-1474

The recipient will be notified in advance of sample shipment.

Shipment of Neonatal Thyroid Tissue Samples:

Thyroid tissue samples will be shipped (ambient conditions) for histopathological and morphometric evaluations to:

Kathleen A. Funk, Ph.D  
Experimental Pathology Laboratories, Inc.  
22866 Shaw Road  
Sterling, Virginia 20166  
Telephone: (703) 471-7060  
Telefax: (703) 471-8447  
E-Mail: [kfunk@epl-inc.com](mailto:kfunk@epl-inc.com)

The recipient will be notified in advance of sample shipment.

Shipment of Neonatal Brain Tissue Samples:

Tissues for neurohistological evaluations will be shipped (ambient conditions) to:

Robert H. Garman, D.V.M., Diplomate, ACVP  
Consultants in Veterinary Pathology  
1909 New Texas Road  
Plumboro, PA 15239  
Telephone: (724) 733-5154  
Telefax: (724) 733-3032  
E-Mail: [vetpathol@cs.com](mailto:vetpathol@cs.com)

The recipient will be notified in advance of sample shipment.

**Scheduled Sacrifice - Part B:**

Pups not selected for continuation on study will be sacrificed on day 5 postpartum for blood and tissue sample collection as described above. The remaining pups will be sacrificed on day 10 postpartum for blood and tissue sample collection as described above. Pups will be retained in neutral buffered 10% formalin.

**Scheduled Sacrifice - Part C:**

Pups not selected for continuation on study will be sacrificed on day 5 postpartum for blood sample collection as described above, and retained in neutral buffered 10% formalin without further analysis.

Pups selected for continuation on study will be sacrificed on day 22 postpartum for blood and tissue sample collection as described above. Pups will be retained in neutral buffered 10% formalin.

**Pups Found Dead on Day 1 Postpartum:**

Pups that die before examination of the litter for pup viability will be evaluated for vital status at birth. The lungs will be removed and immersed in water. Pups with lungs that sink will be identified as stillborn; pups with lungs that float will be identified as liveborn, and to have died shortly after birth. Pups with gross lesions will be preserved in Bouin's solution for possible future evaluation.

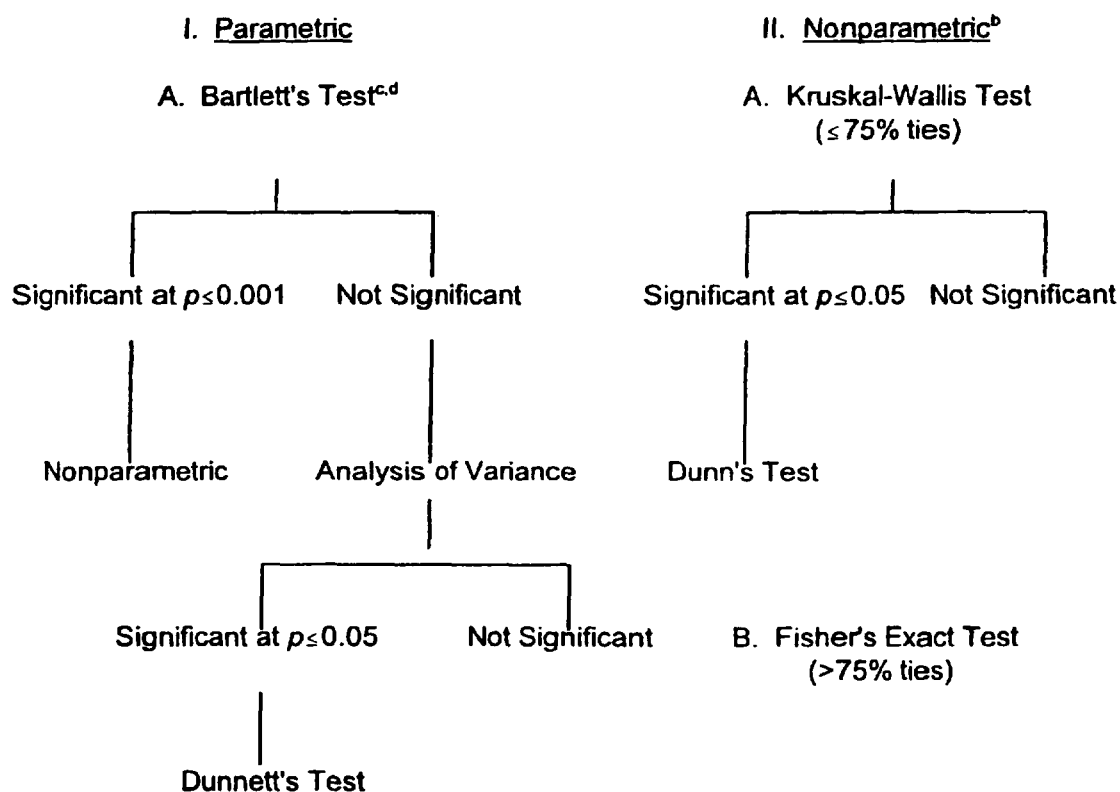
**Pups Found Dead or Moribund on Days 2 to 22 Postpartum:**

Pups found dead or sacrificed because of moribundity will be examined for gross lesions and for the cause of death or the moribund condition. Pups with gross lesions found on days 2 to 4 postpartum will be preserved in Bouin's solution for possible future evaluation; gross lesions of pups found on days 5 to 21 postpartum will be preserved in neutral buffered 10% formalin.



**PROPOSED STATISTICAL METHODS<sup>(8-14)</sup>:**

Averages and percentages will be calculated. Litter values will be used where appropriate. Additional procedures and/or analyses may be performed, if appropriate.

**Type of Test<sup>a</sup>****III. Test for Proportion Data**

Variance Test for Homogeneity  
of the Binomial Distribution

- 
- a. Statistically significant probabilities are reported as either  $p \leq 0.05$  or  $p \leq 0.01$ .
  - b. Proportion data are not included in this category.
  - c. Used only to analyze data for homogeneity of variance.
  - d. Test for homogeneity of variance.

**DATA ACQUISITION, VERIFICATION AND STORAGE:**

Data generated during the course of this study will be recorded either by hand or using the *Argus Reproductive and Developmental Toxicology Data Collection System* and the *Vivarium Temperature and Relative Humidity Monitoring System*. All data will be tabulated, summarized and statistically analyzed using the *Argus Reproductive and Developmental Toxicology Data Collection System*, the *Vivarium Temperature and Relative Humidity Monitoring System*, *Microsoft Excel* [part of Microsoft Office 97 (version SR-2)] and/or *The SAS System* (version 6.12).

Records will be reviewed by the Study Director and/or appropriate management personnel within 21 days after generation. All original records will be stored in the archives of the Testing Facility. All original data will be bound and indexed. A copy of all raw data will be supplied to the Sponsor upon request. Preserved tissues will be stored at the Testing Facility at no charge for one year after mailing of the draft final report, after which time the Sponsor will be contacted to determine the disposition of these materials.

**RECORDS TO BE MAINTAINED:**

Protocol and Amendments.  
Test Substance, Vehicle and/or Reagent Receipt, Preparation and Use.  
Animal Acquisition.  
Randomization Schedules.  
Mating History.  
Treatment (if prescribed by Staff Veterinarian).  
General Comments.  
Clinical Observations and/or General Appearance.  
Blood and Tissue Sample Collection, Processing and Shipment.  
Body Weights.  
Feed Consumption Values.  
Water Consumption Values.  
Caesarean-Sectioning and Fetal Observations.  
Litter Observations.  
Gross Necropsy Observations.  
Organ Weights.  
Photographs (if required).  
Study Maintenance (room and environmental records).  
Feed, Water and Bedding Analyses.  
Packing and/or Shipment Lists.

**KEY PERSONNEL:**

Executive Director of Research: Mildred S. Christian, Ph.D., Fellow, ATS  
Director of Research: Alan M. Hoberman, Ph.D., DABT  
Associate Director of Research and Study Director: Raymond G. York, Ph.D., DABT  
Director of Operations and Compliance: Barbara J. Patterson, B.A.  
Director of Laboratory Operations: John F. Barnett, B.S.  
Director of Study Management: Valerie A. Sharper, M.S.  
Manager of Animal Operations and Chairperson, Institutional Animal Care and Use Committee: Dena C. Lebo, V.M.D.  
Consultant, Veterinary Pathology: Robert H. Garman, D.V.M., Diplomate, ACVP  
Consultant, Veterinary Pathology: Kathleen A. Funk, D.V.M., Ph.D., Diplomate, ACVP

**FINAL REPORT:**

A comprehensive draft final report will be prepared on completion of the study and will be finalized following consultation with the Sponsor. The report will include the following:

Summary and Conclusion.  
Experimental Design and Method.  
Evaluation of Test Results.  
Appendices: Figures, Summary and Individual Tables Summarizing the Above Data, Protocol and Associated Amendments and Deviations, Study Director's GLP Compliance Statement, Reports of Supporting Data (if appropriate) and QAU Statement.

**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE STATEMENT:**

The procedures described in this protocol have been reviewed by the Testing Facility's Institutional Animal Care and Use Committee. All procedures described in this protocol that involve study animals will be conducted in a manner to avoid or minimize discomfort, distress or pain to the animals.

The Sponsor's signature below documents the fact that information concerning the necessity for conducting this study and the fact that this is not an unnecessarily duplicative study may be obtained from the Sponsor. No alternative (*in vitro*) procedures were available for meeting the stated purposes of the study.

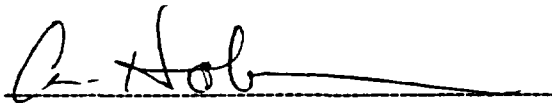
**REFERENCES:**

1. Christian, M.S. and Voytek, P.E. (1982). *In Vivo Reproductive and Mutagenicity Tests*. Environmental Protection Agency, Washington, D.C. National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161.
2. Christian, M.S. (1984). Reproductive toxicity and teratology evaluations of naltrexone (Proceedings of Naltrexone Symposium, New York Academy of Sciences, November 7, 1983), *J. Clin. Psychiat.* 45(9):7-10.
3. Lang, P.L. (1988). *Embryo and Fetal Developmental Toxicity (Teratology) Control Data in the Charles River CrI:CD@BR Rat*. Charles River Laboratories, Inc., Wilmington, MA 01887-0630. (Data base provided by Argus Research Laboratories, Inc.)
4. Institute of Laboratory Animal Resources (1996). *Guide for the Care and Use of Laboratory Animals*. National Academy Press, Washington, D.C.
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6. Staples, R.E. (1974). Detection of visceral alterations in mammalian fetuses. *Teratology* 9(3):A37-38.
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10. Snedecor, G.W. and Cochran, W.G. (1967). Analysis of Variance. *Statistical Methods*, 6th Edition, Iowa State University Press, Ames, pp. 258-275.
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13. Dunn, O.J. (1964). Multiple comparisons using rank sums. *Technometrics* 6(3):241-252.
14. Siegel, S. (1956). *Nonparametric Statistics for the Behavioral Sciences*, McGraw-Hill, New York, pp. 96-104.

**PROTOCOL APPROVAL:**

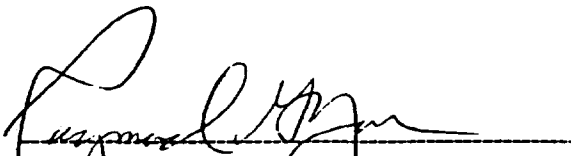
**FOR THE TESTING FACILITY**



Alan M. Hoberman, Ph.D., DABT  
Director of Research

27-Dec-99

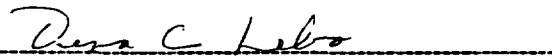
Date



Raymond G. York, Ph.D., DABT  
Associate Director of Research  
Study Director

27-Dec-99

Date



Dena C. Lebo, V.M.D.  
Chairperson, Institutional Animal Care and  
Use Committee

27-Dec-99

Date

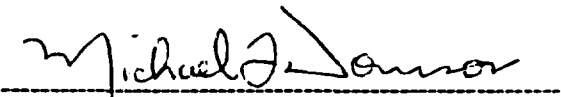
**FOR THE SPONSOR**



Michael F. Girard  
Study Monitor

17 JAN 00

Date



Michael L. Dourson, Ph.D., DABT  
Scientific Advisor

1-25-00

Date

**ATTACHMENT 1**  
**SCHEMATIC OF STUDY DESIGN AND STUDY SCHEDULE**

ATTACHMENT 1

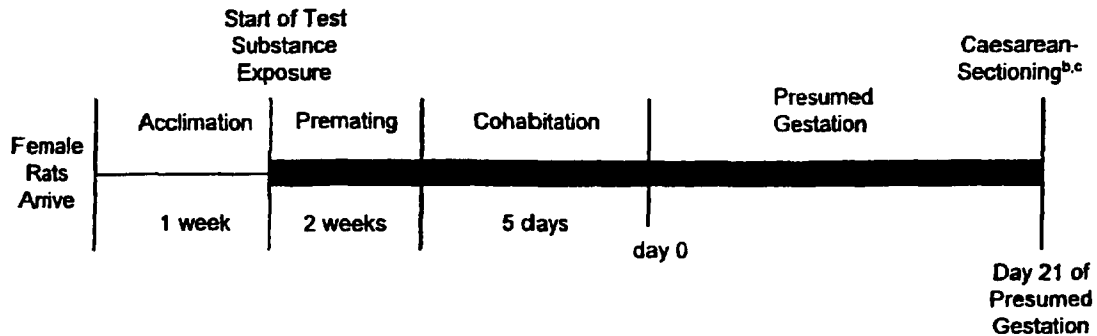
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*(A) R52 OK 11/12/16*

# **STUDY SCHEMATIC**

## **Study Segments A and D\***

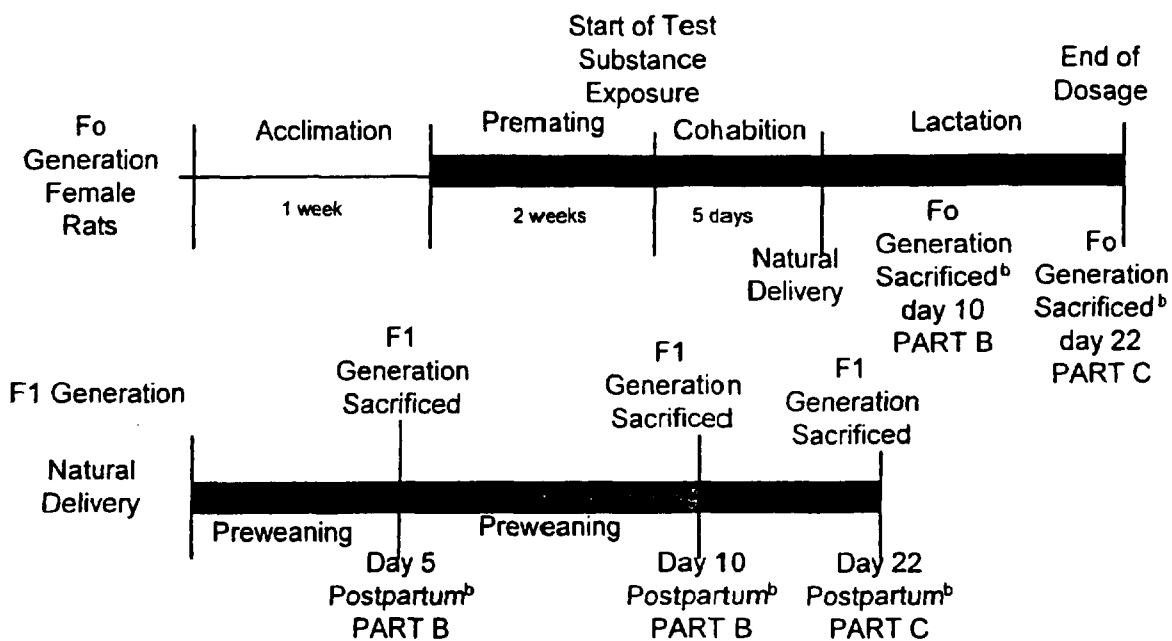


### **■ Test Substance Exposure Period.**

- For additional details see "Tests, Analyses and Measurements" section of the protocol.
- Female rats evaluated for Caesarean-sectioning parameters (e.g. Corpora lutea, implantation sites).
- Tissue and blood samples collection from rats and fetuses assigned to study segment A. Full fetal evaluation for gross, soft tissue and skeletal alterations for fetuses from study segment D.



**Study Segments B and C<sup>a</sup>**



**Thick black bar:** Test Substance Exposure Period through Maternal Milk.

**Thin black bar:** Test Substance Exposure Period.

- For additional details see "Tests, Analyses and Measurements" section of the protocol.
- Blood and tissue sample collection.

**SCHEDULE<sup>a</sup>****Part A**

21 DEC 99	Animal Receipt - Acclimation Begins.
28 DEC 99	Initiation of Test Substance Exposure (Two weeks prior to cohabitation and continuing through the day before sacrifice).
10 JAN 00 PM - 15 JAN 00 AM	Cohabitation Period.
11 JAN 00	First Possible Day 0 of Presumed Gestation.
15 JAN 00	Last Possible Day 0 of Presumed Gestation.
01 FEB 00	First Possible Day 21 of Presumed Gestation Caesarean-sectioning.
05 FEB 00	Last Possible Day 21 of Presumed Gestation Caesarean-sectioning.

**Part B**

21 DEC 99	Animal Receipt - Acclimation Begins.
01 JAN 00	Initiation of Test Substance Exposure (Two weeks prior to cohabitation and continuing through the day before sacrifice).
14 JAN 00 PM - 19 JAN 00 AM	Cohabitation Period.
15 JAN 00	First Possible Day 0 of Presumed Gestation.
19 JAN 00	Last Possible Day 0 of Presumed Gestation.
05 FEB 00	First Possible Delivery (Day 21 of presumed gestation).
13 FEB 00	Last Possible Delivery (Day 25 of presumed gestation).

- 
- a. The study initiation date is the day the Study Director signs the protocol.

09 FEB 00	First Possible Day 25 of Presumed Gestation
	Female Sacrifice.
13 FEB 00	Last Possible Day 25 of Presumed Gestation
	Female Sacrifice.
09 FEB 00	First Possible Day 5 Postpartum Sacrifice.
17 FEB 00	Last Possible Day 5 Postpartum Sacrifice.
14 FEB 00	First Possible Day 10 Postpartum Sacrifice.
22 FEB 00	Last Possible Day 10 Postpartum Sacrifice.

**Part C**

21 DEC 99	Animal Receipt - Acclimation Begins.
28 DEC 99	Initiation of Test Substance Exposure (Two weeks prior to cohabitation and continuing through the day before sacrifice).
10 JAN 00 PM - 15 JAN 00 AM	Cohabitation Period.
11 JAN 00	First Possible Day 0 of Presumed Gestation.
15 JAN 00	Last Possible Day 0 of Presumed Gestation.
01 FEB 00	First Possible Delivery (Day 21 of presumed gestation).
09 FEB 00	Last Possible Delivery (Day 25 of presumed gestation).
05 FEB 00	First Possible Day 25 of Presumed Gestation
	Female Sacrifice.
09 FEB 00	Last Possible Day 25 of Presumed Gestation
	Female Sacrifice.
22 FEB 00	First Possible Day 22 Postpartum Sacrifice.
01 MAR 00	Last Possible Day 22 Postpartum Sacrifice.

**Part D**

25 JAN 00	Animal Receipt - Acclimation Begins.
31 JAN 00	Initiation of Test Substance Exposure (Two weeks prior to cohabitation and continuing through the day before sacrifice).
13 FEB 00 PM - 18 FEB 00 AM	Cohabitation Period.
14 FEB 00	First Possible Day 0 of Presumed Gestation.
18 JAN 00	Last Possible Day 0 of Presumed Gestation.
06 MAR 00	First Possible Day 21 of Presumed Gestation Caesarean-sectioning.
10 MAR 00	Last Possible Day 21 of Presumed Gestation Caesarean-sectioning.
01 JUN 00	Draft Final Report.

**ATTACHMENT 2**  
**MATERIAL SAFETY DATA SHEET**

PRODUCT #: 208507      NAME: AMMONIUM PERCHLORATE, 99.8%  
 MATERIAL SAFETY DATA SHEET, Valid 5/97 - 7/97  
 Printed Monday, July 14, 1997 9:22AM

Sigma Chemical Co. P.O. Box 14508 St. Louis, MO 63178 Phone: 314-771-5765	Aldrich Chemical Co., Inc. 1001 West St. Paul Milwaukee, WI 53233 Phone: 414-273-3850	Fluka Chemical Corp. 1001 West St. Paul Milwaukee, WI 53233 Phone: 414-273-3850
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SECTION 1. - - - - - CHEMICAL IDENTIFICATION- - - - -

CATALOG #: 208507  
 NAME: AMMONIUM PERCHLORATE, 99.8%

SECTION 2. - - - - - COMPOSITION/INFORMATION ON INGREDIENTS - - - - -

CAS #: 7790-98-9  
 MF: H4CLNO4  
 EC NO: 232-235-1

SYNONYMS

AMMONIUM PERCHLORATE (DOT) \* UN0402 (DOT) \* UN1442 (DOT) \*

SECTION 3. - - - - - HAZARDS IDENTIFICATION - - - - -

LABEL PRECAUTIONARY STATEMENTS

EXPLOSIVE  
 HARMFUL  
 HEATING MAY CAUSE AN EXPLOSION.  
 CONTACT WITH COMBUSTIBLE MATERIAL MAY CAUSE FIRE.  
 HARMFUL IF SWALLOWED.  
 IRRITATING TO EYES, RESPIRATORY SYSTEM AND SKIN.  
 STRONG OXIDIZER.  
 KEEP AWAY FROM HEAT  
 IN CASE OF CONTACT WITH EYES, RINSE IMMEDIATELY WITH PLENTY OF  
 WATER AND SEEK MEDICAL ADVICE.  
 TAKE OFF IMMEDIATELY ALL CONTAMINATED CLOTHING.  
 WEAR SUITABLE PROTECTIVE CLOTHING, GLOVES AND EYE/FACE  
 PROTECTION.

SECTION 4. - - - - - FIRST-AID MEASURES- - - - -

IN CASE OF CONTACT, IMMEDIATELY FLUSH EYES OR SKIN WITH COPIOUS  
 AMOUNTS OF WATER FOR AT LEAST 15 MINUTES WHILE REMOVING CONTAMINATED  
 CLOTHING AND SHOES.  
 IF INHALED, REMOVE TO FRESH AIR. IF NOT BREATHING GIVE ARTIFICIAL  
 RESPIRATION. IF BREATHING IS DIFFICULT, GIVE OXYGEN.  
 IF SWALLOWED, WASH OUT MOUTH WITH WATER PROVIDED PERSON IS CONSCIOUS.  
 CALL A PHYSICIAN.  
 DISCARD CONTAMINATED CLOTHING AND SHOES.

SECTION 5. - - - - - FIRE FIGHTING MEASURES - - - - -

EXTINGUISHING MEDIA

WATER SPRAY.

SPECIAL FIREFIGHTING PROCEDURES

WEAR SELF-CONTAINED BREATHING APPARATUS AND PROTECTIVE CLOTHING TO  
 PREVENT CONTACT WITH SKIN AND EYES.  
 USE WATER SPRAY TO COOL FIRE-EXPOSED CONTAINERS.  
 STRONG OXIDIZER.

UNUSUAL FIRE AND EXPLOSIONS HAZARDS

MAY EXPLODE WHEN HEATED.  
 CONTACT WITH OTHER MATERIAL MAY CAUSE FIRE.  
 EMITS TOXIC FUMES UNDER FIRE CONDITIONS.

SECTION 6. - - - - - ACCIDENTAL RELEASE MEASURES- - - - -

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**EVACUATE AREA.**

WEAR SELF-CONTAINED BREATHING APPARATUS, RUBBER BOOTS AND HEAVY RUBBER GLOVES.

COVER WITH DRY LIME OR SODA ASH, PICK UP, KEEP IN A CLOSED CONTAINER AND HOLD FOR WASTE DISPOSAL.

VENTILATE AREA AND WASH SPILL SITE AFTER MATERIAL PICKUP IS COMPLETE.

**SECTION 7. - - - - - HANDLING AND STORAGE- - - - -**

REFER TO SECTION 8.

**ADDITIONAL INFORMATION**

MIXTURES OF AMMONIUM PERCHLORATE WITH SULFUR, ORGANIC MATERIALS, FINELY DIVIDED METALS ARE EXPLOSIVE AND HAVE A SHOCK-SENSITIVITY EQUIVALENT TO PICRIC ACID. IT IS INCOMPATIBLE WITH ALUMINUM, COPPER, CARBON, POTASSIUM PERMANGANATE, POTASSIUM PERIODATE, POTASSIUM DICHROMATE, CADMIUM OXIDE, COPPER OXIDE, ZINC OXIDE, IRON OXIDE, DICHROMIUM TRIOXIDE, COPPER CHROMITE, METAL PERCHLORATES ALL OF WHICH CONSIDERABLY LOWER ITS EXPLOSION TEMPERATURE OF 440 C AND INCREASE ITS SENSITIVITY TO FRICTION. MIXTURES WITH PHOSPHOROUS ARE SHOCK-SENSITIVE. REACTS VIOLENTLY WITH CHLORINE OR CHLORINE DIOXIDE, EXPLOSIONS MAY RESULT.

**SECTION 8. - - - - - EXPOSURE CONTROLS/PERSONAL PROTECTION- - - - -**

WEAR APPROPRIATE NIOSH/MSHA-APPROVED RESPIRATOR, CHEMICAL-RESISTANT GLOVES, SAFETY GOGGLES, OTHER PROTECTIVE CLOTHING.

SAFETY SHOWER AND EYE BATH.

USE ONLY IN A CHEMICAL FUME HOOD.

DO NOT BREATHE DUST.

DO NOT GET IN EYES, ON SKIN, ON CLOTHING.

AVOID PROLONGED OR REPEATED EXPOSURE.

WASH THOROUGHLY AFTER HANDLING.

HARMFUL SOLID.

IRRITANT.

KEEP TIGHTLY CLOSED.

KEEP AWAY FROM COMBUSTIBLE MATERIALS, HEAT, SPARKS, AND OPEN FLAME.

STORE IN A COOL DRY PLACE.

**SECTION 9. - - - - - PHYSICAL AND CHEMICAL PROPERTIES - - - - -**

APPEARANCE AND ODOR

WHITE POWDER

PHYSICAL PROPERTIES

SPECIFIC GRAVITY: 1.950

**SECTION 10. - - - - - STABILITY AND REACTIVITY - - - - -**

INCOMPATIBILITIES

STRONG REDUCING AGENTS

STRONG ACIDS

HEAT-SENSITIVE.

HAZARDOUS COMBUSTION OR DECOMPOSITION PRODUCTS

AMMONIA

**SECTION 11. - - - - - TOXICOLOGICAL INFORMATION - - - - -**

ACUTE EFFECTS

HARMFUL IF SWALLOWED.

MAY BE HARMFUL IF INHALED.

MAY BE HARMFUL IF ABSORBED THROUGH THE SKIN.

CAUSES EYE AND SKIN IRRITATION.

MATERIAL IS IRRITATING TO MUCOUS MEMBRANES AND UPPER

RESPIRATORY TRACT.

RTECS #: SC7520000

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## PERCHLORIC ACID, AMMONIUM SALT

## TOXICITY DATA

ORL-RAT LD50:4200 MG/KG	GISAAA 28 (8), 6, 63
ORL-MUS LD50:1900 MG/KG	GISAAA 26 (8), 8, 63
ORL-RBT LD50:1900 MG/KG	GISAAA 28 (8), 8, 63
ORL-GPG LD50:3310 MG/KG	GISAAA 26 (8), 8, 63

## TARGET ORGAN DATA

BEHAVIORAL (CONVULSIONS OR EFFECT ON SEIZURE THRESHOLD)  
 BEHAVIORAL (EXCITEMENT)  
 BEHAVIORAL (ATAXIA)  
 BEHAVIORAL (COMA)

LUNGS, THORAX OR RESPIRATION (DYSPPNAE)

ONLY SELECTED REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES  
 (RTECS) DATA IS PRESENTED HERE. SEE ACTUAL ENTRY IN RTECS FOR  
 COMPLETE INFORMATION.

SECTION 12. - - - - - ECOLOGICAL INFORMATION - - - - -  
 DATA NOT YET AVAILABLE.

SECTION 13. - - - - - DISPOSAL CONSIDERATIONS - - - - -  
 FOR SMALL QUANTITIES: CAUTIOUSLY ADD TO A LARGE STIRRED EXCESS OF  
 WATER. ADJUST THE PH TO NEUTRAL, SEPARATE ANY INSOLUBLE SOLIDS OR  
 LIQUIDS AND PACKAGE THEM FOR HAZARDOUS-WASTE DISPOSAL. FLUSH THE  
 AQUEOUS SOLUTION DOWN THE DRAIN WITH PLENTY OF WATER. THE HYDROLYSIS  
 AND NEUTRALIZATION REACTIONS MAY GENERATE HEAT AND FUMES WHICH CAN BE  
 CONTROLLED BY THE RATE OF ADDITION.  
 OBSERVE ALL FEDERAL, STATE AND LOCAL ENVIRONMENTAL REGULATIONS.

SECTION 14. - - - - - TRANSPORT INFORMATION - - - - -  
 CONTACT ALDRICH CHEMICAL COMPANY FOR TRANSPORTATION INFORMATION.

SECTION 15. - - - - - REGULATORY INFORMATION - - - - -  
 EUROPEAN INFORMATION

EC INDEX NO: 017-009-00-0

EXPLOSIVE

HARMFUL

F 9

EXPLOSIVE WHEN MIXED WITH COMBUSTIBLE MATERIAL.

R 44

RISK OF EXPLOSION IF HEATED UNDER CONFINEMENT.

S 25

AVOID CONTACT WITH EYES.

S 16

KEEP AWAY FROM SOURCES OF IGNITION - NO SMOKING.

S 27

TAKE OFF IMMEDIATELY ALL CONTAMINATED CLOTHING.

S 24/25

AVOID CONTACT WITH SKIN AND EYES.

## REVIEWS, STANDARDS, AND REGULATIONS

OEL-MAK

NOHS 1974: HZD 80353; NIS 2; TNF 101; NOS 3; TNE 1062

NOES 1983: HZD 80353; NIS 1; TNF 7; NOS 1; TNE 1445; TFE 230

EPA TSCA SECTION 8 (B) CHEMICAL INVENTORY

SECTION 16. - - - - - OTHER INFORMATION - - - - -

THE ABOVE INFORMATION IS BELIEVED TO BE CORRECT BUT DOES NOT PURPORT TO  
 BE ALL INCLUSIVE AND SHALL BE USED ONLY AS A GUIDE. SIGMA, ALDRICH,  
 FLUKA SHALL NOT BE HELD LIABLE FOR ANY DAMAGE RESULTING FROM HANDLING  
 OR FROM CONTACT WITH THE ABOVE PRODUCT. SEE REVERSE SIDE OF INVOICE OR



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**ATTACHMENT 3**  
**TEST SUBSTANCE PREPARATION PROCEDURE**

ATTACHMENT 3

Protocol 1416-003  
Version: 1416-003 (21 DEC 99)  
Page 1 of 2

## TEST SUBSTANCE PREPARATION PROCEDURE

Test Substance: Ammonium Perchlorate  
Vehicle: R.O. Deionized Water

## A. Purpose:

The purpose of this procedure is to provide a method for the preparation of dosage solutions of ammonium perchlorate for oral administration to rats on Argus Research Laboratories, Inc., Study, 1416-003.

## B. General Information:

1. All solution containers will be labeled and color-coded. Each label will specify the protocol number, test substance identification, Argus batch number, concentration, dosage level, preparation date, expiration date and storage conditions.
2. Solutions will be prepared:  

<input type="checkbox"/> Daily	<input type="checkbox"/> Weekly	<input type="checkbox"/> For <input type="text"/> days of use
<input checked="" type="checkbox"/> At Least once Weekly		<input type="checkbox"/> By Sponsor
3. Solutions will be prepared from a stock solution (10 mg/mL, w:v) and diluted to each respective concentration. Stock solution will be prepared as needed. NOTE: Stock solution will be stored refrigerated and may appear cloudy.
4. Safety:  

<input checked="" type="checkbox"/>	Gloves, lab coat, goggles or safety glasses and faceshield
<input type="checkbox"/>	Dust-Mist Respirator
<input checked="" type="checkbox"/>	Half-Face Respirator or/Positive Pressure Hood
<input type="checkbox"/>	Full-Face Respirator/Positive Pressure Hood
<input type="checkbox"/>	Tyvek Sleeves or Tyvek suit
<input checked="" type="checkbox"/>	Prepared in a Fume Hood
<input checked="" type="checkbox"/>	Explosive (avoid contact with metals or reducing agents)
5. Dosage solutions adjusted for % Purity or Correction Factor:  

<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No (Calculations based on 100%)
<input type="checkbox"/> % Activity	<input type="checkbox"/> % Purity <input type="checkbox"/> Correction Factor
6. Sampling requirements: Cited in protocol.

## TEST SUBSTANCE PREPARATION PROCEDURE

7. Storage: Cited in protocol.

## C. Stock Solution Preparation

1. Prepare a stock solution of test substance by accurately weighing the required amount of test substance to an appropriately labeled container (see PREPARATION CALCULATIONS).
2. Add approximately 80% of vehicle to the container (see PREPARATION CALCULATIONS).
3. Q.S. to final volume with vehicle (see PREPARATION CALCULATIONS).
4. Add a stir bar to the container, place on a magnetic stir plate and agitate until test article has mixed.

## D. Dosage Solution Preparation:

1. Measure the required amount of test substance stock solution that is needed for the appropriate dosage level into an appropriately sized, labeled container (see PREPARATION DILUTION CALCULATIONS).
2. Add approximately 80% of vehicle to the container (see PREPARATION DILUTION CALCULATIONS).
3. Q.S. to final volume with vehicle (see PREPARATION DILUTIONS CALCULATIONS).
4. Add a stir bar to the container, place on a magnetic stir plate and agitate until test substance has mixed.
5. Repeat steps (1) through (4) for each concentration.

Written by: Sheila AmernApproved by: R. AobeDate: 12/27/99Clarification: X No    Yes (See attached clarification form.)Initials/Date: MOB 3-20-00

**ATTACHMENT 4**  
**TRIMMING AND WEIGHING OF ADULT RAT THYROID TISSUES**

**TRIMMING AND WEIGHING OF ADULT RAT THYROID TISSUES**

Thyroid glands and trachea are removed intact at necropsy and are trimmed and weighed after at least 48 hours of fixation in neutral buffered 10% formalin. Thyroid glands are trimmed and weighed in a stratified manner (i.e., thyroid glands from two rats per group are processed followed by two rats from the next dosage group).

To trim, a small diameter round applicator is tapered to fit through the trachea such that the trachea with the thyroid gland attached can be moved approximately one-third of the way onto the stick. This provides stability and ease in manipulating the thyroid glands during the trimming process. Thyroid gland trimming is done with the aid of a zoom stereomicroscope (e.g., Olympus, Model BHS). The thyroid glands are removed from the trachea by trimming around the periphery of both lobes and the isthmus and gently separating the thyroid gland from the trachea using a No. 11 surgical blade. After the thyroid gland is removed, it is weighed to four decimal places on an electronic balance (e.g., Mettler, Model No. AE100) and is placed back into fixative; the trachea is discarded.

**ATTACHMENT 5**  
**HISTOPATHOLOGY AND MORPHOMETRIC ANALYSIS**

## HISTOPATHOLOGY AND MORPHOMETRIC ANALYSIS

### Thyroid:

For the histopathologic evaluation, the pathologist will grade each tissue for the degree/severity of hypertrophy and for the degree/severity of hyperplasia separately. The pathologist will submit a Standard Operating Procedure that includes criteria for evaluating thyroid hypertrophy versus hyperplasia to the Sponsor for review prior to the start of the histopathological analysis.

For the morphometric analysis, thyroid follicular lumen area and epithelial cell height will be analyzed. The pathologist will submit a Standard Operating Procedure that addresses the following issues to the Sponsor for review prior to analysis: criteria for selecting follicles to measure; approaches for standardizing subjective elements such as different size, shape and amount of follicle in section; approaches for ensuring that follicle measurements are independent and that the same follicle is not read on multiple sections; and the appropriate statistical analyses to separate treatment effects from variation due to sampling.

### Brain:

For histopathological analysis, the regions of the brain to be examined should be those that are dependent on the development of the thyroid gland. Suggested regions for evaluation include the caudal portion of the corpus callosum, the hippocampus, and the neocortex. Other endpoints in the brain that are dependent on thyroid development include the packing density of cells in the cerebral and cerebellar cortex, and the degree of myelination. The pathologist will submit a Standard Operating Procedure that includes criteria for evaluating various regions of the brain to the Sponsor for review prior to the start of the histopathological analysis.

For the morphometric analysis, a Standard Operating Procedure will be in place to ensure comparability of the plane-of-cut for brain sections to reduce variability.





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905 Sheehy Drive, Building A  
Horsham, PA 19044  
Telephone: (215) 443-8710  
Telefax: (215) 443-8587

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PROTOCOL 1416-003

HORMONE, THYROID AND NEUROHISTOLOGICAL EFFECTS OF ORAL  
(DRINKING WATER) EXPOSURE TO AMMONIUM PERCHLORATE IN PREGNANT  
AND LACTATING RATS AND IN FETUSES AND NURSING PUPS EXPOSED TO  
AMMONIUM PERCHLORATE DURING GESTATION OR VIA MATERNAL MILK

Amendment 1 - 27 January 2000

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1. Shipping Instructions (pages 6 and 14 of the protocol):

[Effective Date: 10 January 2000] The e-mail address for David Mattie, Ph.D., DABT should be David.Mattie@wpafb.af.mil rather than mattie@falcon.al.wpafb.af.mil.

An additional Sponsor contact for formulations analyses will be Latha Narayanan. Her e-mail address is Latha.Narayanan@wpafb.af.mil.

Reason for Change:

This change corrects the protocol and adds an additional contact.

2. Randomization and Cohabitation (page 9 of the protocol):

[Effective Date: 10 January 2000] The sixteen female rats per group per study Segments A, B and C will be randomly selected for sample collections only from female rats that have litters of at least 12 live offspring at the time of Cesarean-sectioning (Part A) or at the time of the first tissue collection (Parts B and C).

Reason for Change:

This change was requested by the Sponsor for clarification of the randomization procedures.

3. Randomization and Cohabitation, Fetal Observations and Neonatal Blood and Tissue Sample Collection - Parts A, B and C (pages 10, 14 and 19 of the protocol):

[Effective Date: 10 January 2000] The thyroid and brain from one male and one female fetus or pup per litter will be selected for histopathological evaluation, rather than selecting one male from each odd-numbered litter and one female from each even-numbered litter.

Reason for Change:

This change was made at the request of the Sponsor in order to increase the number of fetuses and pups sampled from eight to sixteen per group per study segment.

4. Fetal Observations, Part A (page 14 of the protocol):

Fetal thyroids will be shipped for histological evaluation to Kathleen Funk, D.V.M., Ph. D. at Experimental Pathology Laboratories, Inc., at the address cited on page 17 of the protocol. Fetal brains will be shipped for histopathology and morphometry to Robert H. Garman, D.V.M., Consultants in Veterinary Pathology, Monroeville, PA.

Reason for Change:

This change was made to correct the protocol.

5. Rats Found Dead or Moribund (page 18 of the protocol):

[Effective Date: 10 January 2000] Rats found dead or moribund sacrificed will have a complete necropsy. All tissues will be saved in neutral buffered 10% formalin for possible histopathological examination.

Reason for Change:

This change was made at the request of the Sponsor; evaluation of tissues may aid in determination of the cause of death.

6. Trimming and Weighing of Adult and Pup Thyroid Tissues (page 1 of ATTACHMENT 4 to the protocol):

[Effective Date: 10 January 2000] Thyroid glands will be weighed at Experimental Pathology Laboratories, Inc. (EPL). Thyroid glands will be weighed from all rats in one group at a time, rather than in a stratified manner. The same

personnel will weigh the thyroid glands for both the pups and adults in that same dosage group.

Specific information (i.e., manufacturer, size) about the equipment used (zoom stereomicroscope, surgical blade, electronic balance) will not be specified in the protocol.

Trimming - Each thyroid gland will be carefully removed from the trachea for all rats/pups in all dosage groups except for DG 21 fetuses from Part A. For DG 21 fetuses, the thyroids will be left on the trachea and the trachea with thyroid still attached will be laid flat in the cassette.

Weighing - The thyroid glands will be weighed for all adult females and for pups at DL 5, 10 and 22 (Note: the thyroids of DG 21 fetuses are not weighed). Adult and pup thyroids will be weighed according to the method described in ATTACHMENT 4 of the protocol. Weights will be recorded to four decimal places on an electronic balance.

Reason for Change:

Advantages to weighing all thyroids from one group before moving to the next group are: 1) less likelihood of getting animal sequences out of order; 2) organ weight sheets of manageable size may be constructed for each group ahead of time; 3) speed; and 4) identical treatment of pups and adults.

Specifications for equipment will not be included in the protocol, in case a particular specification cannot be met. Information about the equipment will be included in the raw data or the Standard Operating Procedures for EPL.

This clarifies the procedures to be followed in the trimming and weighing of thyroid tissues.

7. Histopathology and Morphometric Analysis (ATTACHMENT 6 to the protocol):

Thyroid

[Effective Date: 10 January 2000] Histopathologic evaluation of thyroid glands will be conducted in stages. The tissues will be examined in the following order: day 5 of lactation (DL 5) pups, DL 10 dams and pups, DL 22 dams and pups and day 21 of gestation (DG 21) dams and fetuses.

Histopathological evaluation of brains will be conducted in stages. The tissues will be examined in the following order: DLs 10 and 22 pups, DL 5 pups and DG 21 fetuses.

All morphometric analysis of the thyroid will be deleted.

Embedding - Each thyroid gland for each rat/pup from all dosage groups at all sacrifices (except DG 21 fetuses) will be embedded with the thyroid lobes placed flat (longitudinally) in one block. The thyroids for DG 21 fetuses will be left on the trachea and the trachea placed longitudinally in the block.

Microtoming - One full face section will be made of each thyroid lobe per slide.

Staining - Each thyroid gland from all rats/pups/fetuses from all sacrifices will be prepared to a standard H&E section.

All thyroids for all rats from all sacrifices will be evaluated microscopically. See attached Procedure for Histopathology of the Thyroid Gland (ATTACHMENT 6).

The final tables for the histopathology report will have enlarged margins (one inch), and the draft final report will be submitted on disk to:

Ray York, Ph.D., DABT  
Argus Research Laboratories, Inc.  
905 Sheehy Drive, Building A  
Horsham, Pennsylvania 19044-1297  
Telephone: (215) 443-8710  
Telefax: (215) 443-8587

The final report will be submitted as a hard copy to the above address.

Reason for Change:


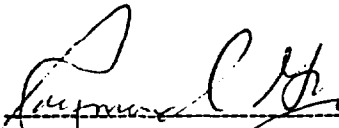
This attachment provides procedures used in the collection, processing and histopathological evaluation the thyroid tissue.

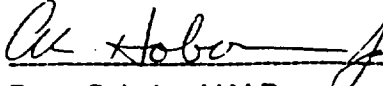
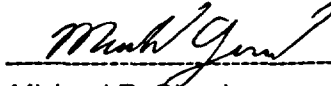
8. ATTACHMENT 7 to the Protocol: Brain Pathology Supplement and Procedure for Histopathology of the Thyroid Gland:

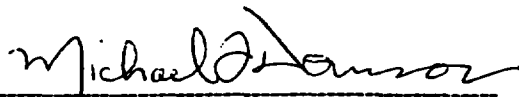
[Effective Date: 10 January 2000] ATTACHMENT 7 has been added to the protocol and is attached to this amendment.

Reason for Change:

This attachment provides procedures used in the collection, processing and histopathological evaluation of brain tissue and the histopathological evaluation of thyroid tissue.

	27 Jan 00		27 Jan 00
Alan M. Hoberman, Ph.D., DABT	Date	Raymond G. York, Ph.D., DABT	Date
Director of Research		Associate Director of Research	
		Study Director	

	27 Jan 00		FEB 11 2000
Dena C. Lebo, V.M.D.	Date	Michael F. Girard	Date
Chairperson, Institutional Animal Care and Use Committee		Study Monitor	

	2-1-00
Michael L. Dourson, Ph.D., DABT	Date
Scientific Advisor	

## Procedure for Histopathology of the Thyroid Gland

### I. Histopathology

#### A. Colloid

1. Coded as DECREASED COLLOID based on either:
  - a. reduction or absence of colloid, or
  - b. pale, lacy or granular colloid

#### B. Follicular Cell Hypertrophy

1. Diagnosed **ONLY** when not associated with follicular cell hyperplasia in the same gland.
2. Coded as AREA AFFECTED
  - a. Grade      % of Follicles Affected
  - 1              1-10
  - 2              11-50
  - 3              51-100

#### C. Follicular Cell Hyperplasia

1. Only diagnosed when there is either stratification (multiple layers) or papillary infolding of single or multiple layers of follicular cells. A capillary may be seen in the core of the papillary infolding. Hypertrophic follicular cells maybe present but will not be diagnosed separately when associated with follicular cell hyperplasia. In such instances, only follicular cell hyperplasia will be diagnosed. Most of the follicles in the affected thyroid gland are small.
2. Coded as AREA AFFECTED
  - a. Grade      % of Follicles Affected
  - 1              1-10
  - 2              11-50
  - 3              51-100
3. Coded as OVERALL SEVERITY
  - a. The average severity of all the affected follicles with follicular cell hyperplasia.
  - b. Grading scale 1-3 where 1=mild, 2=moderate, 3=severe.

4. Coded as GREATEST SEVERITY

- a. The severity grade given to the follicle with the most follicular cell hyperplasia. The severity of the follicular cell hyperplasia based on the complexity of the pattern of hyperplasia and/or multiplicity within the affected thyroid gland follicle.

b. Grade Description

- 1 Simple papillary infolding of follicular epithelium usually with a capillary in its core.
- 2 Multiple papillary infolding with or without stratification of the follicular epithelium in other parts of the same thyroid follicle.
- 3 Hyperplasia of the follicular epithelium having a complex pattern (eg, microfollicular pattern or extensive branching). The follicular cells may appear more basophilic. There is no compression due to the hyperplasia. Generally smaller and less complex than the follicular cell adenomas.

- c. Example: If follicular cell hyperplasia is seen in 8 follicles (4 of minimal severity, 2 of mild severity and 2 with moderate severity):

Area Affected = 1%=1

Overall Severity = 2 (rounded up from 1.75)

Greatest Severity = 3

**Protocol 1416-003, Brain Pathology Supplement**

This supplement clarifies some of the procedures to be followed in the collection and processing of brain tissue from the rats on this study. The supplement is divided into six parts - group size, tissue fixation and collection, gross dissection, histo-technical procedures, morphometric evaluation, and image capture/archiving.

**Group Size:** Brains will be collected from 16 rats/sex in each of the dosage groups excepting for the control group (*i.e.* one rat/sex from each litter). All available control rat brains will be collected.

**Tissue Fixation and Collection:** For gestational day 21 and postpartum day 5 rats, the calvaria will be removed and the heads placed into Bouin's fixative for at least 48 hours, after which the heads will be rinsed in two changes of 50 percent ethanol and then placed into ten percent neutral buffered formalin for additional fixation and storage. For the day 10 and day 22 postpartum rats, the calvaria will be removed and the heads placed into ten percent neutral buffered formalin for fixation and storage.

**Gross Dissection:** In the initial phase of this study, brains will be processed and evaluated only from the day 10 and day 22 postpartum rats. Depending upon the results of this initial valuation, a decision will be made *re:* whether to also examine the brains of the postpartum day 5 and gestational day 21 rats. Initially, only the brains from the high dosage groups (along with an equal number of age-matched control group rat brains), will be dissected and processed for microscopic evaluation. If the results of the microscopic evaluations on these rat brains should indicate that brains from rats in the lower dosage groups also need to be evaluated, additional control group rat brains will also be dissected and processed at the same time as these other brains. Standardized coronal sections will be taken from the brains of the rats killed on postpartum days 5, 10, and 22. Sagittal sections will be prepared from the gestational day 21 rat brains. (Note: The landmarks for these sagittal sections are not elaborated in this supplement.)

There will be five paraffin-embedded tissue blocks (and five or more slides) for each of the brains from rats killed on postpartum days 5, 10, and 22. The first four of these blocks will be step-sectioned, with there being approximately 60 micrometers between each of the step sections. The brain slices in the blocks to be step-sectioned will be taken from the following locations: 1) level of the optic chiasm; 2) level of the infundibulum; 3) level of the mammillary body; 4) midpoint of the cerebellum. All remaining brain sections (with the number of these extra sections varying depending upon the age of the rats) will be multiply embedded within the fifth tissue block. This fifth block will not be step-sectioned. All sections will be embedded with their anterior faces down in the block (*i.e.* representing the faces to be sectioned) with the exception of the olfactory bulbs. These will be embedded lengthwise (for a sagittal section).



**Histo-technical Procedures:** The brain sections from the postpartum day 10 rats will be stained with hematoxylin and eosin. The brain sections from the postpartum day 22 rats will be stained with hematoxylin and eosin, as well as with luxol fast blue/cresyl violet (for myelin as well as cell bodies).

**Morphometric Evaluation:** Multiple linear measurements will be performed on three of the four step-sectioned coronal brain slices using a calibrated ocular micrometer. The following linear measurements will be taken from the specified coronal sections:

Level of the optic chiasm:

- 1) Thickness of the frontal cortex of the cerebrum.
- 2) Thickness of the parietal cortex of the cerebrum.
- 3) Diagonal width of the caudate putamen and underlying globus pallidus.
- 4) Thickness of the corpus callosum taken at the level of the external granular layer of the overlying cingulate cortex.

Level of the infundibulum:

- 5) Thickness of the hippocampus at the level of the dentate gyrus, extending from its ventral aspect (adjacent to the thalamus) over to the alveus hippocampus.
- 6) Thickness of the granule neuron layer of the dentate gyrus.
- 7) Thickness of the CA1 pyramidal neuron layer.
- 8) Thickness of the CA3 pyramidal neuron layer.

Level of the midpoint of the cerebellum:

- 9) Maximal thickness of the cerebellar cortex at the midline, extending from the roof of the fourth ventricle to the superior surface of the cerebellar cortex. This measurement will be taken in a section which includes the deep cerebellar nuclei.
- 10) Thickness of the external germinal layer of the cerebellum (postpartum day 10 rats, but not the postpartum day 22 rats).

All measurements, excepting for #9 and #10, will be taken from both the left side and right side of the respective brain section and these measurements recorded separately in order to judge the degree of variation by side. For measurement #9, approximately six separate measurements will be taken across the superior aspect of the cerebellar cortex. Although all of these thicknesses (of the external germinal layer) will be recorded, only the mean value will be used for statistical evaluation.

**Image Capture/Archiving:** At the same time that the microscopic measurements are performed, full-face images of the coronal brain slices will be captured digitally using a PathScan Enabler and a Polaroid SprintScan 35 film scanner. The brain sections will be scanned at a resolution of 2700 dpi and saved as "tiff" files. These digital images will be archived on a CD-R disc and will be available for evaluation of consistency of section level or

ATTACHMENT 7

Protocol 1416-003

Page 3

for additional measurement (directly on a computer monitor, with an image analysis program, or on an image print-out). "Thumbnail" images of these digitized coronal slices will be included with the raw data (or, if desired, placed in the report.) One of the archived images will include lines showing the location and angle of the linear measurements that have been taken. In addition, the level of each forebrain image will be referenced according to the plates presented in *A Stereotaxic Atlas of the Developing Rat Brain* by Nancy M. Sherwood and Paola S. Timiras (University of California Press, 1970).



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Telefax: (215) 443-8587

# PROTOCOL 1416-003

## HORMONE, THYROID AND NEUROHISTOLOGICAL EFFECTS OF ORAL (DRINKING WATER) EXPOSURE TO AMMONIUM PERCHLORATE IN PREGNANT AND LACTATING RATS AND IN FETUSES AND NURSING PUPS EXPOSED TO AMMONIUM PERCHLORATE DURING GESTATION OR VIA MATERNAL MILK

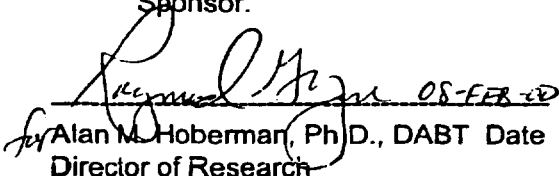
Amendment 2 - 8 February 2000

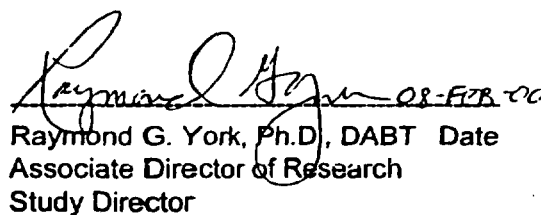
1. Neonatal Blood and Tissue Sample Collection - Parts B and C (page 19 of the protocol):

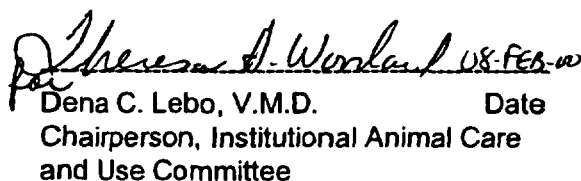
[Effective Date: 4 February 2000] Blood samples for evaluation of thyroid hormones will be collected by cardiac puncture following carbon dioxide asphyxiation for the pups sacrificed on day 5 postpartum.

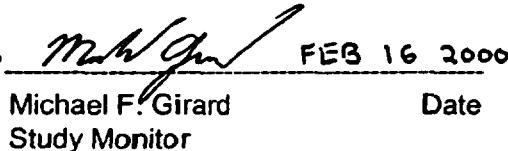
### Reason for Change:

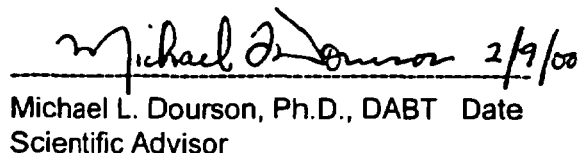
This change was made to accommodate the volume of blood requested by the Sponsor.

  
for Alan M. Hoberman, Ph.D., DABT Date  
Director of Research

  
Raymond G. York, Ph.D., DABT Date  
Associate Director of Research  
Study Director

  
Dena C. Lebo, V.M.D. Date  
Chairperson, Institutional Animal Care  
and Use Committee

  
Michael F. Girard Date  
Study Monitor

  
Michael L. Dourson, Ph.D., DABT Date  
Scientific Advisor



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PROTOCOL 1416-003

HORMONE, THYROID AND NEUROHISTOLOGICAL EFFECTS OF ORAL  
(DRINKING WATER) EXPOSURE TO AMMONIUM PERCHLORATE IN PREGNANT  
AND LACTATING RATS AND IN FETUSES AND NURSING PUPS EXPOSED TO  
AMMONIUM PERCHLORATE DURING GESTATION OR VIA MATERNAL MILK

Amendment 3 - 7 March 2000

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1. Neonatal Blood and Tissue Sample Collection - Parts B and C (page 19 of the protocol):

[Effective Date: 10 February 2000] Blood samples for evaluation of thyroid hormones will be collected by cardiac puncture following carbon dioxide asphyxiation for the pups sacrificed on day 10 postpartum.

Reason for Change:

This change was made to accommodate the volume of blood requested by the Sponsor.

2. Randomization and Cohabitation (page 9 and ATTACHMENT 1 to the protocol):

Following 15 days, rather than 2 weeks, of exposure to the test substance, the female rats in Part D will be cohabited with breeder male rats, one male rat per female rat. The new schedule will be as follows:

**Any revisions to this finalized amendment must be made by subsequent amendment.**

25 JAN 00	Animal Receipt - Acclimation Begins.
31 JAN 00	Initiation of Test Substance Exposure (Two weeks prior to cohabitation and continuing through the day before sacrifice).
14 FEB 00 PM - 19 FEB 00 AM	Cohabitation Period.
15 FEB 00	First Possible Day 0 of Presumed Gestation.
19 JAN 00	Last Possible Day 0 of Presumed Gestation.
07 MAR 00	First Possible Day 21 of Presumed Gestation Caesarean-sectioning.
11 MAR 00	Last Possible Day 21 of Presumed Gestation Caesarean-sectioning.
01 JUN 00	Draft Final Report.

Reason for Change:

To facilitate laboratory scheduling so that cohabitation is started on a Monday instead of a Sunday.

**Any revisions to this finalized amendment must be made by subsequent amendment.**

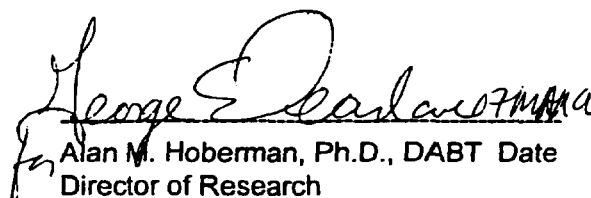
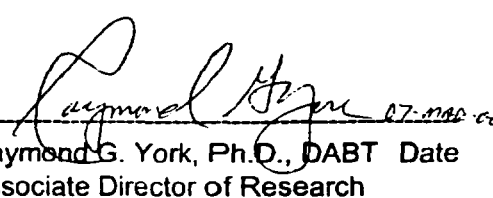
3. Shipment of Maternal Thyroid Tissue Samples (page 17 of the protocol):

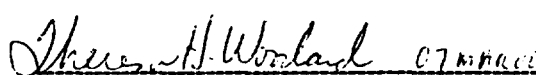

The correct address for Kathleen Funk is as follows:

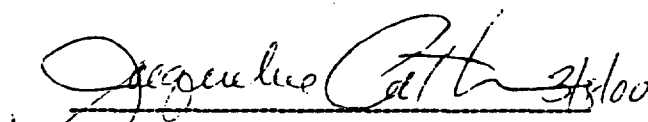
Kathleen Funk, D.V.M., Ph. D.  
Experimental Pathology Laboratories, Inc.  
22866 Shaw Road  
Sterling, Virginia 20166  
Telephone: (703) 471-7060 Ext. 206  
Telefax: (703) 471-8447  
E-Mail: [kfunk@epl-inc.com](mailto:kfunk@epl-inc.com)

Reason for Change:

This change corrects a typographical error in the protocol.

	
Alan M. Hoberman, Ph.D., DABT Date Director of Research	Raymond G. York, Ph.D., DABT Date Associate Director of Research Study Director

	
Dena C. Lebo, V.M.D. Date Chairperson, Institutional Animal Care and Use Committee	Michael F. Girard Date Study Monitor


Michael L. Dourson, Ph.D., DABT Date Scientific Advisor

Any revisions to this finalized amendment must be made by subsequent amendment.



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PROTOCOL 1416-003

HORMONE, THYROID AND NEUROHISTOLOGICAL EFFECTS OF ORAL  
(DRINKING WATER) EXPOSURE TO AMMONIUM PERCHLORATE IN PREGNANT  
AND LACTATING RATS AND IN FETUSES AND NURSING PUPS EXPOSED TO  
AMMONIUM PERCHLORATE DURING GESTATION OR VIA MATERNAL MILK

Amendment 4 - 15 March 2000

---

1. Randomization and Cohabitation (ATTACHMENT 1 and Amendment 3 to the protocol):

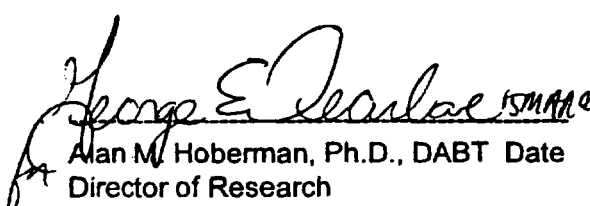
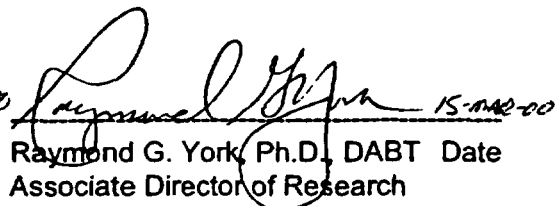
The female rats in Part D will be cohabited with breeder male rats, one male rat per female rat until at least 20 pregnant females are allocated to each exposure group. The new schedule will be as follows:

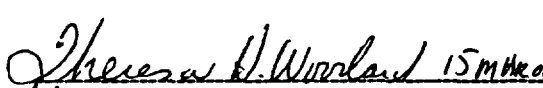

25 JAN 00	Animal Receipt - Acclimation Begins.
31 JAN 00	Initiation of Test Substance Exposure (Two weeks prior to cohabitation and continuing through the day before sacrifice).
14 FEB 00 PM - 23 FEB 00 AM	Cohabitation Period.
15 FEB 00	First Possible Day 0 of Presumed Gestation.
23 FEB 00	Last Possible Day 0 of Presumed Gestation.
07 MAR 00	First Possible Day 21 of Presumed Gestation Caesarean-sectioning.
15 MAR 00	Last Possible Day 21 of Presumed Gestation Caesarean-sectioning.
01 JUN 00	Draft Final Report.

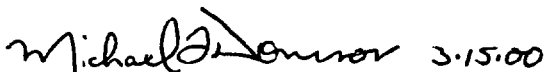
Any revisions to this finalized amendment must be made by subsequent amendment.

Reason for Change:

To ensure enough pregnant females will be available for the study.

 Alan M. Hoberman, Ph.D., DABT Date Director of Research	 Raymond G. York, Ph.D., DABT Date Associate Director of Research Study Director
---	---

 Dena C. Lebo, V.M.D. Date Chairperson, Institutional Animal Care and Use Committee	 Michael F. Girard Date Study Monitor
---	---

  
 Michael L. Dourson, Ph.D., DABT Date  
 Scientific Advisor

Any revisions to this finalized amendment must be made by subsequent amendment.





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905 Sheehy Drive, Building A  
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Telefax: (215) 443-8587

# PROTOCOL 1416-003

## HORMONE, THYROID AND NEUROHISTOLOGICAL EFFECTS OF ORAL (DRINKING WATER) EXPOSURE TO AMMONIUM PERCHLORATE IN PREGNANT AND LACTATING RATS AND IN FETUSES AND NURSING PUPS EXPOSED TO AMMONIUM PERCHLORATE DURING GESTATION OR VIA MATERNAL MILK


Amendment 5 - 20 April 2000.

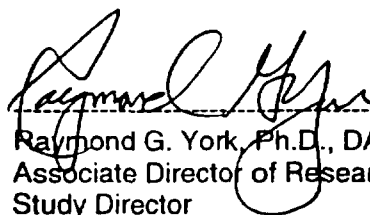
### 1. Final Report (page 24 of the protocol):

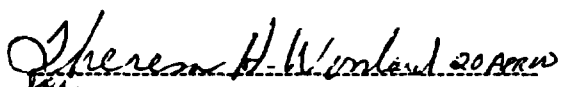
The final report will be issued as two stand-alone GLP compliant reports. One report will retain the original study title and will present the methodology and results from Parts A, B and C of the study. The other report will be entitled "Oral (Drinking Water) Developmental Toxicity Study of Ammonium Perchlorate in Rats" and will present the methodology and results from Part D of the study. Mail dates for both draft reports remain June 1, 2000.

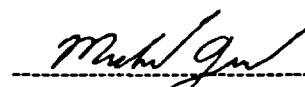
### Reason for Change:

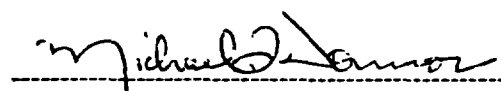
This change was made at the Sponsor's request.

 20 APR 00  
Alan M. Hoberman, Ph.D., DABT Date  
Director of Research

 20 APR 00  
Raymond G. York, Ph.D., DABT Date  
Associate Director of Research  
Study Director

 20 APR 00  
Dena C. Lebo, V.M.D. Date  
Chairperson, Institutional Animal Care  
and Use Committee

 28 APR 00  
Michael F. Girard Date  
Study Monitor

 21 April 00  
Michael L. Dourson, Ph.D., DABT Date  
Scientific Advisor

Any revisions to this finalized amendment must be made by subsequent amendment.



Argus Research Laboratories, Inc.  
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PROTOCOL 1416-003

HORMONE, THYROID AND NEUROHISTOLOGICAL EFFECTS OF ORAL  
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AND LACTATING RATS AND IN FETUSES AND NURSING PUPS EXPOSED TO  
AMMONIUM PERCHLORATE DURING GESTATION OR VIA MATERNAL MILK

Amendment 6 - 7 July 2000

---

1. Test Substance (page 4 of the protocol):

The Ammonium Perchlorate (CAS Number 7790-98-9), lot number 03907LF, was obtained from Aldrich Chemical Company, Milwaukee, Wisconsin.

Reason for Change:

The source and lot number were to be documented by amendment.

2. Randomization and Cohabitation (page 9 of the protocol):

[Effective Date: 19 January 2000] The cohabitation period for Part B of the study will consist of a maximum of ten days, rather than five days.

Reason for Change:

The cohabitation period for was extended in order to provide a sufficient number of pregnant rats for Part B of the study.

3. Data Acquisition, Verification and Storage (page 23 of the protocol):

[Effective Date: 22 December 1999] The *Primedica Argus Reproductive and Developmental Toxicology Data Collection System* was used to collect, tabulate, summarize and statistically analyze data, rather than the *Argus Reproductive and Developmental Toxicology Data Collection System*.

Reason for Change:

This change corrects the protocol.

4. Procedure for Histopathology of the Thyroid Gland (ATTACHMENT 6 and Amendment 1 to the protocol):

The Procedure for Histopathology of the Thyroid Gland in Amendment 1 has been replaced by the appended ATTACHMENT 6.

Reason for Change:


This change was added by the Veterinary Pathologist.

5. ATTACHMENT 7 to the Protocol; Brain Pathology Supplement and Procedure for Histopathology of the Thyroid Gland (page 4 of Amendment 1 to the protocol):

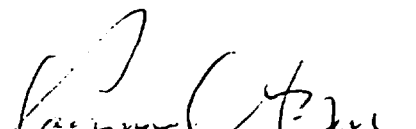
Conduct of neurohistological/morphological evaluations of fetal brains will be added for the lower dosage groups, beginning with Group IV (1.0 mg/kg/day) and continuing down until a no-effect level is determined.

Reason for Change:

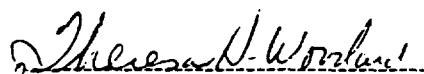
Additional evaluations were required based on the results of evaluations of fetal brains for the high dosage group (30.0 mg/kg/day).

 7 JUL 00


Alan M. Hoberman, Ph.D., DABT      Date  
Director of Research

 07-JUL-00

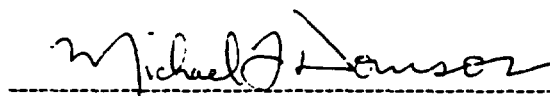
Raymond G. York, Ph.D., DABT      Date  
Associate Director of Research  
Study Director

 07 JUL 00

Dena C. Lebo, V.M.D.      Date  
Chairperson, Institutional Animal Care  
and Use Committee

 23 JUL 00

Michael F. Girard      Date  
Study Monitor

 17/7/00

Michael L. Dourson, Ph.D., DABT      Date  
Scientific Advisor

Any revisions to this finalized amendment must be made by subsequent amendment.

## Procedure for Histopathology of the Thyroid Gland

### I. Histopathology

#### A. Colloid

1. Coded as DECREASED COLLOID based on either:
  - a. Grade      % of follicles affected
    1.      1-10
    2.      11-50
    3.      51-100

#### B. Follicular Cell Hypertrophy

1. Diagnosed separately from follicular cell hyperplasia and based on size of the cell (cytoplasmic to nuclear ratio)
  - a. Grading scale 1-3 where 1=minimal, 2=mild, 3=moderate to severe

#### C. Follicular Cell Hyperplasia

1. Only diagnosed when there is either stratification (multiple layers) or papillary infolding of single or multiple layers of follicular cells. Follicles at the perimeter of the examined thyroid lobes were generally excluded.
2. Coded as AREA AFFECTED
  - a. Grade      % of Follicles Affected
    1.      1-10
    2.      11-50
    3.      51-100
3. Coded as OVERALL SEVERITY
  - a. The average severity of all the affected follicles with follicular cell hyperplasia.
  - b. Grading scale 1-3 where 1=minimal, 2=mild, 3=moderate to severe.
4. Coded as GREATEST SEVERITY
  - a. The severity grade given to the follicle with the most follicular cell hyperplasia. The severity of the follicular cell hyperplasia based on the complexity of the pattern of hyperplasia and/or multiplicity within the affected thyroid gland follicle.

- b. Grade description
1. Simple papillary infolding of follicular epithelium usually with a capillary in its core.
  2. Multiple papillary infolding with or without stratification of the follicular epithelium in other parts of the same thyroid follicle.
  3. Hyperplasia of the follicular epithelium having a complex pattern (eg, microfollicular pattern or extensive branching). The follicular cells may appear more basophilic. There is no compression due to the hyperplasia. Generally smaller and less complex than the follicular cell adenomas.
- c. Example: If follicular cell hyperplasia is seen in 8 follicles (4 of minimal severity, 2 of mild severity and 2 of moderate severity):
- Area Affected = 1%=1  
Overall Severity = 2 (rounded up from 1.75)  
Greatest Severity = 3

APPENDIX D  
CERTIFICATE OF ANALYSIS

# CERTIFICATE OF ANALYSIS

---

PO NBR:

ARGUS RESEARCH LABS  
TRISH KELLY  
FAX 215 443 8587

PRODUCT NUMBER: 20850-7

LOT NUMBER: 03907LF

PRODUCT NAME: AMMONIUM PERCHLORATE, 99.8%

FORMULA:  $\text{NH}_4\text{ClO}_4$ 

FORMULA WEIGHT: 117.49

APPEARANCE

WHITE POWDER

X-RAY DIFFRACTION  
PATTERN

CONFORMS TO STANDARD PATTERN.

TITRATION

0.05 %  $\text{H}_2\text{O}$ 

TRACE ANALYSIS, ICP

CA	660	PPM
F	260	PPM
NA	50	PPM
MG	6	PPM
BA	4	PPM
SR	0.4	PPM

ALDRICH CHEMICAL COMPANY  
DAVID SWESSEL  
JUNE 2, 2000



chemists helping chemists in research &amp; industry

**aldrich chemical co.**

P.O. Box 355, Milwaukee, Wisconsin 53201 USA • (414) 273-3850 • FAX (414) 273-4979

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APPENDIX E  
ENVIRONMENTAL AND HUSBANDRY REPORTS



## ARGUS

<b>Temperature and Relative Humidity Report</b> <b>Location: Room 26</b> <b>Protocol Number: 1416003</b>			
Range of Dates: 25-Jan-2000 16:30 to 07-Feb-2000 15:59			
<b>Target Range:</b> <b>Species: RAT</b>  <b>Total Number of Days:</b> <b>Total Number of Hours:</b> <b>Total Number of Data Points:</b>	<b>Temperature</b> 64°F to 79°F  14 311.25 311	<b>Relative Humidity</b> 30% to 70%  14 311.25 311	
<b>Mean (± SD):</b>	69.7      (± 0.5)	47.9      (± 2.3)	
<b>Maximum:</b>	71.0	54.7	
<b>Median:</b>	69.7	48.0	
<b>Minimum:</b>	68.3	40.2	
<b>Number of Points in Range (%):</b>	311      (100.0)	311      (100.0)	
<b>Number of Points High (%):</b>	0      (0.0)	0      (0.0)	
<b>Number of Points Low (%):</b>	0      (0.0)	0      (0.0)	

Report Generated: 18-May-2000 at 10:38

COMMENTS: \_\_\_\_\_

\_\_\_\_\_

REVIEWED BY: C. C. C. DATE: 5-18-00

## ARGUS

<b>Temperature and Relative Humidity Report</b> <b>Location: Room 14</b> <b>Protocol Number: 1416003</b>			
Range of Dates: 07-Feb-2000 15:00 to 24-Feb-2000 14:59			
<b>Target Range:</b> <b>Species: RAT</b>	<b>Temperature</b> 64°F to 79°F		<b>Relative Humidity</b> 30% to 70%
<b>Total Number of Days:</b>	18		18
<b>Total Number of Hours:</b>	407.75		407.75
<b>Total Number of Data Points:</b>	408		408
<b>Mean (± SD):</b>	70.0	(± 3.6)	59.0 (± 2.3)
<b>Maximum:</b>	100.0		75.4
<b>Median:</b>	69.5		58.8
<b>Minimum:</b>	68.6		55.2
<b>Number of Points in Range (%):</b>	400	(98.0)	403 (98.8)
<b>Number of Points High (%):</b>	8	(2.0)	5 (1.2)
<b>Number of Points Low (%):</b>	0	(0.0)	0 (0.0)

Report Generated: 18-May-2000 at 10:40

COMMENTS: \_\_\_\_\_

\_\_\_\_\_

 REVIEWED BY: C. Culver DATE: 5-18-00

## ARGUS

---

**Temperature Deviations Report**  
**Location: Room 14****Protocol Number: 1416003**

---

**Range of Dates: 07-Feb-2000 15:00 to 24-Feb-2000 14:59**

---

**Temperature Target Range:**  
**Species: RAT**

64°F to 79°F

Date	Time	Temp.	Date	Time	Temp.
10-Feb-2000	14:00	84.7 H			
16-Feb-2000	09:00	84.6 H			
16-Feb-2000	10:00	100.0 H <sup>Q</sup>			
16-Feb-2000	11:00	100.0 H <sup>Q</sup>			
16-Feb-2000	12:00	100.0 H <sup>Q</sup>			
16-Feb-2000	13:00	100.0 H <sup>Q</sup>			
16-Feb-2000	14:00	100.0 H <sup>Q</sup>			
16-Feb-2000	15:00	84.8 H			

---

H = Value out of range - High    L = Value out of range - Low  
Temp. = Temperature °F

**Report Generated: 18-May-2000 at 10:42**

☒ These deviations did not adversely affect the outcome or interpretation of the study.

☐ The following deviation(s) impacted on the outcome of the study as described:

Study Director: 

Date: 31-May-00

① False temperature recordings as indicated by facility deviation. SIB 5/5/00

## ARGUS

---

**Relative Humidity Deviations Report**  
**Location: Room 14****Protocol Number: 1416003**

---

**Range of Dates: 07-Feb-2000 15:00 to 24-Feb-2000 14:59**

---

**Humidity Target Range:**  
**Species: RAT**

30% to 70%

Date	Time	R.H.	Date	Time	R.H.
16-Feb-2000	10:00	75.0 H			
16-Feb-2000	11:00	75.0 H			
16-Feb-2000	12:00	75.0 H			
16-Feb-2000	13:00	75.4 H			
16-Feb-2000	14:00	75.4 H			

---

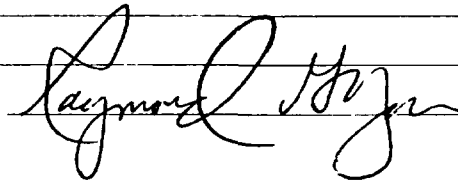
H = Value out of range - High    L = Value out of range - Low  
R.H. = Relative Humidity (%)

**Report Generated: 18-May-2000 at 10:43**

☒ These deviations did not adversely affect the outcome or interpretation of the study.

☐ The following deviation(s) impacted on the outcome of the study as described:

Study Director: \_\_\_\_\_



Date: 31-MAY-00

## ARGUS

<b>Temperature and Relative Humidity Report</b> <b>Location: Room 25</b> <b>Protocol Number: 1416003</b>		
<b>Range of Dates: 24-Feb-2000 14:40 to 13-Mar-2000 13:59</b>		
<b>Target Range:</b> <b>Species: RAT</b>  <b>Total Number of Days:</b> <b>Total Number of Hours:</b> <b>Total Number of Data Points:</b>	<b>Temperature</b> 64°F to 79°F  19 431.0 432	<b>Relative Humidity</b> 30% to 70%  19 431.0 432
<b>Mean (± SD):</b>	67.7      (± 0.9)	58.1      (± 1.9)
<b>Maximum:</b>	70.8	64.8
<b>Median:</b>	67.6	58.2
<b>Minimum:</b>	65.1	51.2
<b>Number of Points in Range (%):</b>	432      (100.0)	432      (100.0)
<b>Number of Points High (%):</b>	0      (0.0)	0      (0.0)
<b>Number of Points Low (%):</b>	0      (0.0)	0      (0.0)

Report Generated: 18-May-2000 at 10:45

COMMENTS: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

REVIEWED BY: C. Cullen      DATE: 5-18-00

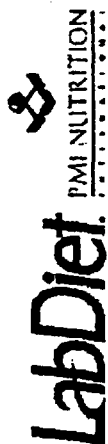
## ARGUS

<b>Temperature and Relative Humidity Report</b> <b>Location: Room 28-29</b> <b>Protocol Number: 1416003</b>			
Range of Dates: 13-Mar-2000 13:00 to 15-Mar-2000 07:59			
<b>Target Range:</b> <b>Species: RAT</b>  <b>Total Number of Days:</b> <b>Total Number of Hours:</b> <b>Total Number of Data Points:</b>	<b>Temperature</b> 64°F to 79°F  3 42.75 43	<b>Relative Humidity</b> 30% to 70%  3 42.75 43	
<b>Mean (± SD):</b>	72.2      (± 0.7)	51.8      (± 4.0)	
<b>Maximum:</b>	73.9	60.3	
<b>Median:</b>	72.0	51.6	
<b>Minimum:</b>	71.2	43.0	
<b>Number of Points In Range (%):</b>	43      (100.0)	43      (100.0)	
<b>Number of Points High (%):</b>	0      (0.0)	0      (0.0)	
<b>Number of Points Low (%):</b>	0      (0.0)	0      (0.0)	

Report Generated: 18-May-2000 at 10:47

COMMENTS: \_\_\_\_\_

REVIEWED BY: C. CulverDATE: 5-18-00



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Certified Analysis Retrieval

Product Code: 5002M Product Desc: CERTIFIED RODENT DIET MEAL  
Lab Number: L9916286-1 Lot Code: SEP 26 99 1B Entered: 09/28/1999

Assay	Analysis	Units
PROTEIN (N X 6.25)	21.1	%
FAT (ACID HYDRO.)	5.59	%
FIBER (CRUDE)	4.3	%
ARSENIC	LESS THAN 0.2	PPM
CADMIUM	0.082	PPM
CALCIUM	0.993	%
LEAD	0.18	PPM
MERCURY	LESS THAN 0.025	PPM
PHOSPHORUS	0.699	%
SELENIUM	0.3261	PPM

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18 5.22.00

ORGANOPHOSPHATES	PPM	PPM	
Diazinon	LESS THAN 0.02	Disulfoton	LESS THAN 0.02
Ethion	LESS THAN 0.02	Malathion	LESS THAN 0.02
Methyl Parathion	LESS THAN 0.02	Parathion	LESS THAN 0.02
Thimet	LESS THAN 0.02	Thiodan	LESS THAN 0.02
Trithion	LESS THAN 0.02		

Ellen Anderson 12/1/99

REVIEWED BY: DATE

PESTICIDES AND PCB		PPM	
Aldrin	LESS THAN 0.02	Alpha-BHC	LESS THAN 0.02
Beta-BHC	LESS THAN 0.02	Chlordane	LESS THAN 0.02
DDE	LESS THAN 0.02	DDT	LESS THAN 0.02
Delta-BHC	LESS THAN 0.02	Dieldrin	LESS THAN 0.02
Endrin	LESS THAN 0.02	HCB	LESS THAN 0.02
Heptachlor	LESS THAN 0.02	Heptachlor Epoxide	LESS THAN 0.02
Lindane	LESS THAN 0.02	Methoxychlor	LESS THAN 0.02
Mirex	LESS THAN 0.02	PCB	LESS THAN 0.15
Aflatoxin	Aflatoxins	LESS THAN 5 PPB	

For additional information, please contact:

- (1) For assay methodology - Michael J. Murphy 314-982-2383
- (2) For nutritional interpretation - Dr. Dorrance Haught 314-768-4362
- (3) All other questions - Richmond, IN Manufacturing Plant 765-962-9561

The term "Less Than" is used to signify the lower limit of quantitation of the procedure under the conditions employed. The use of the term "Less Than" does not imply that traces of analyte were present.

LabDiet is a registered trademark of PMI Nutrition International. All certified products are manufactured under strict supervision in our ISO 9002 drug and estrogen free plant in Richmond, Indiana.

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Erin Anderson 12/1/99  
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ARGUS 1416-003

11/21/99 1:36 PM



Certified Papers Retrieval

[http://www.labdiet.com/certified/pwa\\_spc002.asp](http://www.labdiet.com/certified/pwa_spc002.asp)

## Return to Certified Analysis Administration

Product Code: 5002M  
 Product Desc: CERTIFIED RODENT DIET MEAL  
 Lab Number: L9919495-3  
 Lot Code: NOV 22 99 3C  
 Entered: 11/24/99

EXACT COPY  
 JB 5-22-02

Assay	Analysis	Units
PROTEIN (N X 6.25)	21.1	%
FAT (ACID HYDRO.)	5.64	%
FIBER (CRUDE)	4.51	%
ARSENIC	LESS THAN 0.2	PPM
CADMIUM	0.061	PPM
CALCIUM	0.937	%
LEAD	0.181	PPM
MERCURY	LESS THAN 0.025	PPM
PHOSPHORUS	0.629	%
SELENIUM	0.309	ppm

ORGANOPHOSPHATES	PPM	ORGANOPHOSPHATES	PPM
Diazinon	LESS THAN 0.02	Disulfoton	LESS THAN 0.02
Ethion	LESS THAN 0.02	Malathion	LESS THAN 0.02
Methyl Parathion	LESS THAN 0.02	Parathion	LESS THAN 0.02
Thimet	LESS THAN 0.02	Thiodan	LESS THAN 0.02
Trithion	LESS THAN 0.02		

PESTICIDES AND PCB	PPM	PESTICIDES AND PCB	PPM
Aldrin	LESS THAN 0.02	Alpha-BHC	LESS THAN 0.02
Beta-BHC	LESS THAN 0.02	Chlordane	LESS THAN 0.02
DDE	LESS THAN 0.02	DDT	LESS THAN 0.02
Delta-BHC	LESS THAN 0.02	Dieldrin	LESS THAN 0.02
Endrin	LESS THAN 0.02	HCB	LESS THAN 0.02
Heptachlor	LESS THAN 0.02	Heptachlor Epoxide	LESS THAN 0.02
Lindane	LESS THAN 0.02	Methoxychlor	LESS THAN 0.02
Mirex	LESS THAN 0.02	PCB	LESS THAN 0.15

Aflatoxin	Aflatoxin	LESS THAN 5 PPB
-----------	-----------	-----------------

No notes.

For additional information, please contact:

- 1) Michael J. Murphy at (314) 982-2383 -- for assay methodology
- 2) Dr. Dorrance Haught at (314) 768-4362 -- for nutritional interpretation
- 3) Richmond, IN Sales Office at (765) 962-9561 -- all other questions

REVIEWED BY: Eileen Anderson

11/21/00

DATE



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JB 5-22-00

Certified Papers Retrieval

Page 1 of 1

turn to Certified Analysis Retrie

Product 5002M  
Code:  
Product CERTIFIED RODENT DIET MEAL  
Desc:  
Lab  
Number: L9920535-1  
Lot  
Code: DEC 13 99 3A  
Entered: 12/15/99

Assay	Analysis	Units
PROTEIN (N X 6.25)	21.2%	
FAT (ACID HYDRO.)	6.46%	
FIBER (CRUDE)	4.16%	
ARSENIC	0.2217	PPM
CADMIUM	0.058	PPM
CALCIUM	0.916%	
LEAD	0.116	PPM
MERCURY	LESS THAN 0.025	PPM
PHOSPHORUS	0.613%	
SELENIUM	0.3192	PPM

ORGANOPHOSPHATES	PPM	ORGANOPHOSPHATES	PPM
Diazinon	LESS THAN 0.02	Disulfoton	LESS THAN 0.02
Ethion	LESS THAN 0.02	Malathion	0.08
Methyl Parathion	LESS THAN 0.02	Parathion	LESS THAN 0.02
Thimet	LESS THAN 0.02	Thiodan	LESS THAN 0.02
Trithion	LESS THAN 0.02		

PESTICIDES AND PCB	PPM	PESTICIDES AND PCB	PPM
Aldrin	LESS THAN 0.02	Alpha-BHC	LESS THAN 0.02
Beta-BHC	LESS THAN 0.02	Chlordane	LESS THAN 0.02
DDE	LESS THAN 0.02	DDT	LESS THAN 0.02
Delta-BHC	LESS THAN 0.02	Dieldrin	LESS THAN 0.02
Endrin	LESS THAN 0.02	HCB	LESS THAN 0.02
Heptachlor	LESS THAN 0.02	Heptachlor Epoxide	LESS THAN 0.02
Lindane	LESS THAN 0.02	Methoxychlor	LESS THAN 0.02
Mirex	LESS THAN 0.02	PCB	LESS THAN 0.15

Aflatoxin	Aflatoxins	LESS THAN 5 PPB	
-----------	------------	-----------------	--

No notes.

For additional information, please contact:

- 1) Michael J. Murphy at (314) 982-2383 -- for assay methodology
- 2) Dr. Dorrance Haught at (314) 768-4362 -- for nutritional interpretation
- 3) Richmond, IN Sales Office at (765) 962-9561 -- all other questions

The term "Less Than" is used to signify the lower limit of quantitation of the procedure under the conditions employed.  
The use of the term "Less Than" does not imply that traces of analyte were present.

3/8/00  
DATE  
REVIEWED BY: *Eileen Anderson*

**Analysis Report**

Page: 1 of 3

**LLI Sample No. WW 3315341**  
 Collected: 01/31/00 at 09:42 by PA

Submitted: 01/31/00 Reported: 02/15/00  
 Discard: 03/17/00

#1 Formulation Lab 905 Sheehy Grab Water Sample

Account No: 02423

Primedica Argus  
 905 Sheehy Drive, Ste. A  
 Horsham PA 19044-1297

P.O. 1134962  
 Rel.

**EXACT COPY**

JIS 5-22-00

CAT NO.	ANALYSIS NAME	AS RECEIVED		UNITS
		RESULTS	LIMIT OF QUANTITATION	
0178	Pesticides/PCB's in Water			See Page 2
1856	Herbicides in Water			See Page 3
0224	Chloride	< 2.0	2.0	mg/l
0228	Sulfate	< 5.0	5.0	mg/l
0368	Nitrate Nitrogen	< 0.50	0.50	mg/l
1504	Fluoride	< 0.50	0.50	mg/l
1505	Bromide	< 2.5	2.5	mg/l
1506	Nitrite Nitrogen	< 0.50	0.50	mg/l
7322	Ortho-phosphate	< 5.0	5.0	mg/l

Commonwealth of Pennsylvania Lab Certification No. 36-037

*D. Lelso*  
*3/6/00*

1 COPY TO Primedica Argus

ATTN: Mr. Julian Gulbinski

Questions? Contact your Client Services Representative  
 at (717) 656-2300

02:35:09 D 0001 3  
 047 0.00 00067700 ASR000 700965



Lancaster Laboratories  
 2425 New Holland Pike  
 PO Box 12425  
 Lancaster, PA 17605-2425  
 717 656 2300 Fax: 717-656-2631

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 See reverse side for explanation of symbols and abbreviations.

Respectfully Submitted  
 Jenifer E. Hess, B.S.  
 Group Leader Pesticides/PCBs

2216 Rev 3/23/95

**Analysis Report****Lancaster Laboratories**  
Where quality is a science.

Page: 2 of 3

**LLI Sample No. WW 3315341**  
Collected: 01/31/00 at 09:42 by PASubmitted: 01/31/00 Reported: 02/15/00  
Discard: 03/17/00

#1 Formulation Lab 905 Sheehy Grab Water Sample

Account No: 02423

Primedica Argus  
905 Sheehy Drive, Ste. A  
Horsham PA 19044-1297P.O. 1134962  
Ref.**EXACT COPY**

385.22.00

CAT NO.	ANALYSIS NAME	AS RECEIVED		
		RESULTS	LIMIT OF QUANTITATION	UNITS
Pesticides/PCB's in Water				
1902	Alpha BHC	< 0.0095	0.0095	ug/l
1903	Beta BHC	< 0.0095	0.0095	ug/l
0453	Gamma BHC - Lindane	< 0.0095	0.0095	ug/l
1904	Delta BHC	< 0.0095	0.0095	ug/l
0454	Heptachlor	< 0.0095	0.0095	ug/l
0455	Aldrin	< 0.0095	0.0095	ug/l
1905	Heptachlor Epoxide	< 0.0095	0.0095	ug/l
1906	DDE	< 0.0095	0.0095	ug/l
1907	DDD	< 0.0095	0.0095	ug/l
0478	DDT	< 0.0095	0.0095	ug/l
0469	Dieldrin	< 0.0095	0.0095	ug/l
0477	Endrin	< 0.0095	0.0095	ug/l
1908	Chlordane	< 0.29	0.29	ug/l
1909	Toxaphene	< 3.8	3.8	ug/l
1910	Endosulfan I	< 0.0095	0.0095	ug/l
1911	Endosulfan II	< 0.0095	0.0095	ug/l
1912	Endosulfan Sulfate	< 0.029	0.029	ug/l
0638	Endrin Aldehyde	< 0.095	0.095	ug/l
1913	PCB-1016	< 1.0	1.0	ug/l
1914	PCB-1221	< 1.0	1.0	ug/l
1915	PCB-1232	< 1.0	1.0	ug/l
1916	PCB-1242	< 1.0	1.0	ug/l
1917	PCB-1248	< 1.0	1.0	ug/l
1918	PCB-1254	< 1.0	1.0	ug/l
1919	PCB-1260	< 1.0	1.0	ug/l

D. L. Lobo  
3/6/00Questions? Contact your Client Services Representative  
at (717) 656-2300Lancaster Laboratories  
2425 New Holland Pike  
PO Box 12425Lancaster, PA 17605-2425  
717-656-2300 Fax: 717-656-2331Lancaster Laboratories is a subsidiary of Thermo TerraTech Inc., a Thermo Electron Company.  
See internet site for pronunciation of symbols and abbreviations.Respectfully Submitted  
Jenifer E. Hess, B.S.  
Group Leader Pesticides/PCBs

2215 Rev. 3/23/95

**Analysis Report**

Page: 3 of 3

LLI Sample No. WW 3315341  
Collected: 01/31/00 at 09:42 by PA

Submitted: 01/31/00 Reported: 02/15/00  
Discard: 03/17/00

#1 Formulation Lab 905 Sheehy Grab Water Sample

Account No: 02423

Primedica Argus  
905 Sheehy Drive, Ste. A  
Horsham PA 19044-1297

P.O. 1134962  
Rel.

**EXACT COPY**

JB 5-22-00

CAT NO.	ANALYSIS NAME	AS RECEIVED		
		RESULTS	LIMIT OF QUANTITATION	UNITS
Herbicides in Water				
1857	2,4-D	< 0.48	0.48	ug/l
1858	2,4,5-TP	< 0.048	0.048	ug/l
5286	2,4,5-T	< 0.048	0.048	ug/l
5287	Dalapon	< 1.2	1.2	ug/l
5288	Dinoseb	< 0.24	0.24	ug/l
5289	Dicamba	< 0.29	0.29	ug/l
5290	MCPP	< 190.	190.	ug/l
5291	MCPA	< 190.	190.	ug/l
5292	2,4-DP (Dichlorprop)	< 0.48	0.48	ug/l
5293	2,4-DB	< 0.48	0.48	ug/l
8103	Pentachlorophenol	< 0.05	0.05	ug/l

*D. Lelso*  
*3/6/00*

Questions? Contact your Client Services Representative  
at (717) 656-2300



Lancaster Laboratories  
2425 New Holland Pike  
PO Box 12425

Lancaster, PA 17605-2425  
717-656-2300 Fax 717-656-2351

Respectfully Submitted  
Jenifer E. Hess, B.S.  
Group Leader Pesticides/PCBs

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For complete list of abbreviations and symbols and interpretations

2215 Rev. 3/23/99

## Analysis Report



Page: 1 of 3

LLI Sample No. WW 3315342  
Collected: 01/31/00 at 09:40 by PA

Submitted: 01/31/00 Reported: 02/15/00  
Discard: 03/17/00

#2 Formulation Lab 905 Sheehy Bldg. F Grab Water  
Sample

Account No: 02423

Primedica Argus  
905 Sheehy Drive, Ste. A  
Horsham PA 19044-1297

P.O. 1134962  
Rel.

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JB 5-22-00

CAT NO.	ANALYSIS NAME	AS RECEIVED		UNITS
		RESULTS	LIMIT OF QUANTITATION	
0178	Pesticides/PCB's in Water			See Page 2
1856	Herbicides in Water			See Page 3
0224	Chloride	< 2.0	2.0	mg/l
0228	Sulfate	< 5.0	5.0	mg/l
0368	Nitrate Nitrogen	< 0.50	0.50	mg/l
1504	Fluoride	< 0.50	0.50	mg/l
1505	Bromide	< 2.5	2.5	mg/l
1506	Nitrite Nitrogen	< 0.50	0.50	mg/l
7322	Ortho-phosphate	< 5.0	5.0	mg/l

Commonwealth of Pennsylvania Lab Certification No. 36-037

*D. Lelo*  
*3/6/00*

1 COPY TO Primedica Argus

ATTN: Mr. Julian Gulbinski

Questions? Contact your Client Services Representative  
at (717) 656-2300

02:35:24 D 0001 3  
047 0.00 00067700 ASR000 700965



Lancaster Laboratories  
2425 New Holland Pike  
PO Box 12425  
Lancaster, PA 17605-2425  
717 656-2300 Fax 717 656-2581

Respectfully Submitted  
Jennifer E. Hess, B.S.  
Group Leader Pesticides/PCBs

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2215 Rev 3/23/95

## Analysis Report



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Page: 2 of 3

LLI Sample No. WW 3315342  
Collected: 01/31/00 at 09:40 by PA

Submitted: 01/31/00 Reported: 02/15/00  
Discard: 03/17/00

#2 Formulation Lab 905 Sheehy Bldg. F Grab Water  
Sample

Account No: 02423

Primedica Argus  
905 Sheehy Drive, Ste. A  
Horsham PA 19044-1297

P.O. 1134962  
Rel.

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JB 5 22-00

CAT NO.	ANALYSIS NAME	AS RECEIVED		
		RESULTS	LIMIT OF QUANTITATION	UNITS
Pesticides/PCB's in Water				
1902	Alpha BHC	< 0.0095	0.0095	ug/l
1903	Beta BHC	< 0.0095	0.0095	ug/l
0453	Gamma BHC - Lindane	< 0.0095	0.0095	ug/l
1904	Delta BHC	< 0.0095	0.0095	ug/l
0454	Heptachlor	< 0.0095	0.0095	ug/l
0455	Aldrin	< 0.0095	0.0095	ug/l
1905	Heptachlor Epoxide	< 0.0095	0.0095	ug/l
1906	DDE	< 0.0095	0.0095	ug/l
1907	DDD	< 0.0095	0.0095	ug/l
0478	DDT	< 0.0095	0.0095	ug/l
0469	Dieldrin	< 0.0095	0.0095	ug/l
0477	Endrin	< 0.0095	0.0095	ug/l
1908	Chlordane	< 0.29	0.29	ug/l
1909	Toxaphene	< 3.8	3.8	ug/l
1910	Endosulfan I	< 0.0095	0.0095	ug/l
1911	Endosulfan II	< 0.0095	0.0095	ug/l
1912	Endosulfan Sulfate	< 0.029	0.029	ug/l
0638	Endrin Aldehyde	< 0.095	0.095	ug/l
1913	PCB-1016	< 1.0	1.0	ug/l
1914	PCB-1221	< 1.0	1.0	ug/l
1915	PCB-1232	< 1.0	1.0	ug/l
1916	PCB-1242	< 1.0	1.0	ug/l
1917	PCB-1248	< 1.0	1.0	ug/l
1918	PCB-1254	< 1.0	1.0	ug/l
1919	PCB-1260	< 1.0	1.0	ug/l

*D. Helbo*  
3/6/00

Questions? Contact your Client Services Representative  
at (717) 656-2300



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2425 New Holland Pike  
PO Box 12425

Lancaster, PA 17605-2425  
717 656-2300 Fax 717 656-2381

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Respectfully Submitted  
Jenifer E. Hess, B.S.  
Group Leader Pesticides/PCBs

2216 Rev. 3/23/90

## Analysis Report



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Where quality is a science.

Page: 3 of 3

LLI Sample No. WW 3315342

Collected: 01/31/00 at 09:40 by PA

Submitted: 01/31/00 Reported: 02/15/00  
Discard: 03/17/00

#2 Formulation Lab 905 Sheehy Bldg. F Grab Water  
Sample

Account No: 02423

Primedica Argus  
905 Sheehy Drive, Ste. A  
Horsham PA 19044-1297

P.O. 1134962  
Rel.

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JB 5-22-00

CAT NO.	ANALYSIS NAME	AS RECEIVED		UNITS
		RESULTS	LIMIT OF QUANTITATION	
Herbicides in Water				
1857	2,4-D	< 0.48	0.48	ug/l
1858	2,4,5-TP	< 0.048	0.048	ug/l
5286	2,4,5-T	< 0.048	0.048	ug/l
5287	Dalapon	< 1.2	1.2	ug/l
5288	Dinoseb	< 0.24	0.24	ug/l
5289	Dicamba	< 0.29	0.29	ug/l
5290	MCP	< 190.	190.	ug/l
5291	MCPA	< 190.	190.	ug/l
5292	2,4-DP (Dichlorprop)	< 0.48	0.48	ug/l
5293	2,4-DB	< 0.48	0.48	ug/l
8103	Pentachloropheno]	< 0.05	0.05	ug/l

*D. Hess*  
3/6/00

Questions? Contact your Client Services Representative  
at (717) 656-2300



Lancaster Laboratories  
2425 New Holland Pike  
PO Box 12425  
Lancaster, PA 17605-2425  
717-656-2300 Fax 717-656-7621

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Respectfully Submitted  
Jenifer E. Hess, B.S.  
Group Leader Pesticides/PCBs

2216 Rev 3/21/99



## Explanation of Symbols and Abbreviations

The following defines common symbols and abbreviations used in reporting technical data:

<b>N.D.</b>	none detected	<b>BMQL</b>	Below Minimum Quantitation Level
<b>TNTC</b>	Too Numerous To Count	<b>MPN</b>	Most Probable Number
<b>IU</b>	International Units	<b>CP Units</b>	cobalt-chloroplatinate units
<b>umhos/cm</b>	micromhos/cm	<b>NTU</b>	nephelometric turbidity units
<b>C</b>	degrees Celsius	<b>F</b>	degrees Fahrenheit
<b>Cal</b>	(diet) calories	<b>lb.</b>	pound(s)
<b>meq</b>	milliequivalents	<b>kg</b>	kilogram(s)
<b>g</b>	gram(s)	<b>mg</b>	milligram(s)
<b>ug</b>	microgram(s)	<b>l</b>	liter(s)
<b>ml</b>	milliliter(s)	<b>ul</b>	microliter(s)
<b>m3</b>	cubic meter(s)	<b>fib &gt;5 um/ml</b>	fibers greater than 5 microns in length per ml
<b>&lt;</b>	less than - The number following the sign is the <u>limit of quantitation</u> , the smallest amount of analyte which can be reliably determined using this specific test.		
<b>&gt;</b>	greater than		
<b>ppm</b>	parts per million - One ppm is equivalent to one milligram per kilogram (mg/kg), or one gram per million grams. For aqueous liquids, ppm is usually taken to be equivalent to milligrams per liter (mg/l), because one liter of water has a weight very close to a kilogram. For gases or vapors, one ppm is equivalent to one microliter of gas per liter of gas.		
<b>ppb</b>	parts per billion		
<b>Dry weight basis</b>	Results printed under this heading have been adjusted for moisture content. This increases the analyte weight concentration to approximate the value present in a similar sample without moisture.		

### U.S. EPA data qualifiers:

Organic Qualifiers		Inorganic Qualifiers	
<b>A</b>	TIC is a possible aldol-condensation product	<b>B</b>	Value is <CRDL, but ≥IDL
<b>B</b>	Analyte was also detected in the blank	<b>E</b>	Estimated due to interference
<b>C</b>	Pesticide result confirmed by GC/MS	<b>M</b>	Duplicate injection precision not met
<b>D</b>	Compound quantitated on a diluted sample	<b>N</b>	Spike sample not within control limits
<b>E</b>	Concentration exceeds the calibration range of the instrument	<b>S</b>	Method of standard additions (MSA) used for calculation
<b>J</b>	Estimated value	<b>U</b>	Compound was not detected
<b>N</b>	Presumptive evidence of a compound (TICs only)	<b>W</b>	Post digestion spike out of control limits
<b>P</b>	Concentration difference between primary confirmation columns >25%	<b>*</b>	Duplicate analysis not within control limits
<b>U</b>	Compound was not detected	<b>+</b>	Correlation coefficient for MSA <0.995
<b>X,Y,Z</b>	Defined in case narrative		

Tests results relate only to the sample tested. Clients should be aware that a critical step in a chemical or microbiological analysis is the collection of the sample. Unless the sample analyzed is truly representative of the bulk of material involved, the test results will be meaningless. If you have questions regarding the proper techniques of collecting samples, please contact us. We cannot be held responsible for sample integrity, however, unless sampling has been performed by a member of our staff. This report shall not be reproduced except in full, without the written approval of the laboratory.

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ANALYTICAL LABORATORIES, INC.  
P.O. Box 319  
Chalfont, PA 18914  
(215) 723-6466

## SAMPLE ANALYSIS REPORT

Customer: Argus Research Inc.  
905 Sheehy Dr., Building A  
Horsham, PA 19044  
Attn. Dena Lebo  
Attn: 215-443-8710  
FAX : 215-443-8587

Sample Number : 2182-00A  
Date Sampled : 01/24/00  
Time Sampled : 1215  
Date Received : 01/24/00  
Sampled By : RW

Sample source: Chem. Lab  
905 B Sheehy Drive @ Dr 1/31/00

## ANALYTICAL RESULTS

Water Safety Classification: No Coliform bacteria were detected. Therefore, the water supply, at the time of sampling, meets the EPA and DEP drinking water standards for this parameter.

<u>Parameter</u>	<u>MCL</u>	<u>Result</u>
Total Coliform Bacteria, counts/100 ml	< 1	< 1
Noncoliform bacteria, counts/100 ml	< 1	< 1
Total Chlorine, mg/l as Cl	< 0.1	< 0.1

*D. Lebo*  
1/31/00

Results which are outside the "Maximum Contaminant Level" (MCL) established under the "Safe Drinking Water Act" are marked with asterisks (\*\*).

## Symbol key:

TNTC - Too numerous to count (> 200)  
< - Less than  
mg/l - milligrams/liter

PA DEP #09-332  
NJ Cert #77847

*Maryann E. Fedock*  
Maryann E. Fedock / President

## ANALYTICAL LABORATORIES, INC.

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Chalfont, PA 18914  
(215) 723-6466

## SAMPLE ANALYSIS REPORT

Customer: Argus Research Inc.  
905 Sheehy Dr., Building A  
Horsham, PA 19044  
Attn. Dena Lebo  
Attn: 215-443-8710  
FAX : 215-443-8587

Sample Number : 2182-00C  
Date Sampled : 01/24/00  
Time Sampled : 1215  
Date Received : 01/24/00  
Sampled By : RW

Sample source: Chem. Lab II  
905 F Sheehy Drive <sup>DD</sup> 1/31/00

## ANALYTICAL RESULTS

Water Safety Classification: No Coliform bacteria were detected. Therefore, the water supply, at the time of sampling, meets the EPA and DEP drinking water standards for this parameter.

ParameterMCLResult

Total Coliform Bacteria, counts/100 ml	< 1	< 1
Noncoliform bacteria, counts/100 ml		< 1
Total Chlorine, mg/l as Cl		< 0.1

*D. Lebo*  
1/31/00

Results which are outside the "Maximum Contaminant Level" (MCL) established under the "Safe Drinking Water Act" are marked with asterisks (\*\*).

## Symbol key:

NTC - Too numerous to count (> 200)  
- Less than  
mg/l - milligrams/liter

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NJ Cert #77847

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Chalfont, PA 18914  
(215) 723-6466

## SAMPLE ANALYSIS REPORT

Customer: Argus Research Inc.  
905 Sheehy Dr., Building A  
Horsham, PA 19044  
Attn. Dena Lebo  
Attn: 215-443-8710  
FAX : 215-443-8587

Sample Number : 2182-00D  
Date Sampled : 01/24/00  
Time Sampled : 1215  
Date Received : 01/24/00  
Sampled By : RW

Sample source: Necropsy  
905 Sheehy Drive <sup>ADN</sup> 1/31/00

## ANALYTICAL RESULTS

Water Safety Classification: No Coliform bacteria were detected. Therefore, the water supply, at the time of sampling, meets the EPA and DEP drinking water standards for this parameter.

<u>Parameter</u>	<u>MCL</u>	<u>Result</u>
Total Coliform Bacteria, counts/100 ml	< 1	< 1
Noncoliform bacteria, counts/100 ml	< 1	< 1
Total Chlorine, mg/l as Cl		< 0.1

*D. Lebo*  
1/31/00

Results which are outside the "Maximum Contaminant Level" (MCL) established under the "Safe Drinking Water Act" are marked with asterisks (\*\*).

## Symbol key:

TNTC - Too numerous to count (> 200)  
< - Less than  
mg/l - milligrams/liter

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Chalfont, PA 18914  
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## SAMPLE ANALYSIS REPORT

Customer: Argus Research Inc.  
905 Sheehy Dr., Building A  
Horsham, PA 19044  
Attn. Dena Lebo  
Attn: 215-443-8710  
FAX : 215-443-8587

Sample Number : 2335-00A  
Date Sampled : 02/16/00  
Time Sampled : 0930  
Date Received : 02/16/00  
Sampled By : RW

Sample source: Chem. Lab

905 B Sheehy Drive <sup>DHL</sup> 2/22/00

## ANALYTICAL RESULTS

Water Safety Classification: No Coliform bacteria were detected. Therefore, the water supply, at the time of sampling, meets the EPA and DEP drinking water standards for this parameter.

<u>Parameter</u>	<u>MCL</u>	<u>Result</u>
Total Coliform Bacteria, counts/100 ml	< 1	< 1
Coliform bacteria, counts/100 ml	< 1	< 1
Total Chlorine, mg/l as Cl		< 0.1

*D. Hls*  
2/22/00

Results which are outside the "Maximum Contaminant Level" (MCL) established under the "Safe Drinking Water Act" are marked with asterisks (\*\*).

## Symbol key:

TNTC - Too numerous to count (> 200)  
< - Less than  
mg/l - milligrams/liter

PA DEP #09-332  
N.T. Cert #77847

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(215) 723-6466

## SAMPLE ANALYSIS REPORT

Customer: Argus Research Inc.  
905 Sheehy Dr., Building A  
Horsham, PA 19044  
Attn. Dena Lebo  
Attn: 215-443-8710  
FAX : 215-443-8587

Sample Number : 2335-00B  
Date Sampled : 02/16/00  
Time Sampled : 0930  
Date Received : 02/16/00  
Sampled By : RW

Sample source: Rm. 35

905 Sheehy Drive <sup>Ⓟ</sup>DL  
2/22/00

## ANALYTICAL RESULTS

Water Safety Classification: No Coliform bacteria were detected. Therefore, the water supply, at the time of sampling, meets the EPA and DEP drinking water standards for this parameter.

ParameterMCLResult

Total Coliform Bacteria, counts/100 ml < 1  
Fecal coliform bacteria, counts/100 ml  
Total Chlorine, mg/l as Cl

< 1  
< 1  
< 0.1

*D. Lebo*  
2/22/00

Results which are outside the "Maximum Contaminant Level" (MCL) established under the "Safe Drinking Water Act" are marked with asterisks (\*\*).

## Symbol key:

TNTC - Too numerous to count (> 200)

< - Less than

mg/l - milligrams/liter

PA DEP #09-332  
N° Cert #77847

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Chalfont, PA 18914  
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## SAMPLE ANALYSIS REPORT

Customer: Argus Research Inc.  
905 Sheehy Dr., Building A  
Horsham, PA 19044  
Attn. Dena Lebo  
Attn: 215-443-8710  
FAX : 215-443-8587

Sample Number : 2335-00D  
Date Sampled : 02/16/00  
Time Sampled : 0930  
Date Received : 02/16/00  
Sampled By : RW

Sample source: Chem. Lab #2 *① DL 2/22/00*  
905 F Sheehy Drive

## ANALYTICAL RESULTS

Water Safety Classification: No Coliform bacteria were detected. Therefore, the water supply, at the time of sampling, meets the EPA and DEP drinking water standards for this parameter.

<u>Parameter</u>	<u>MCL</u>	<u>Result</u>
Total Coliform Bacteria, counts/100 ml	< 1	< 1
Coliform bacteria, counts/100 ml		< 1
Total Chlorine, mg/l as Cl		< 0.1

*D. Lebo*  
2/22/00

Results which are outside the "Maximum Contaminant Level" (MCL) established under the "Safe Drinking Water Act" are marked with asterisks (\*\*).

## Symbol key:

TNTC - Too numerous to count (> 200)  
< - Less than  
mg/l - milligrams/liter

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NT Cert #77847

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(215) 723-6466

## SAMPLE ANALYSIS REPORT

Customer: Argus Research Inc.  
905 Sheehy Dr., Building A  
Horsham, PA 19044  
Attn. Dena Lebo  
Attn: 215-443-8710  
FAX : 215-443-8587

Sample Number : 2478-00A  
Date Sampled : 03/10/00  
Time Sampled : 1415  
Date Received : 03/10/00  
Sampled By : RW

Sample source: Chem. Lab

905 Sheehy Drive *DAK* 3/22/00

## ANALYTICAL RESULTS

Water Safety Classification: No Coliform bacteria were detected. Therefore, the water supply, at the time of sampling, meets the EPA and DEP drinking water standards for this parameter.

<u>Parameter</u>	<u>MCL</u>	<u>Result</u>
Total Coliform Bacteria, counts/100 ml	< 1	< 1
Coliform bacteria, counts/100 ml	< 1	< 1
Total Chlorine, mg/l as Cl		< 0.1

*D. Lebo*  
3/22/00

Results which are outside the "Maximum Contaminant Level" (MCL) established under the "Safe Drinking Water Act" are marked with asterisks (\*\*).

Symbol key:  
N/A - Too numerous to count (> 200)  
- Less than  
mg/l - milligrams/liter

PA DEP #09-332  
PA Cert #77847

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P.O. Box 319  
Chalfont, PA 18914  
(215) 723-6466

## SAMPLE ANALYSIS REPORT

Customer: Argus Research Inc.  
905 Sheehy Dr., Building A  
Horsham, PA 19044  
Attn: Dena Lebo  
Attn: 215-443-8710  
FAX : 215-443-8587

Sample Number : 2478-00B  
Date Sampled : 03/10/00  
Time Sampled : 1415  
Date Received : 03/10/00  
Sampled By : RW

Sample source: Rm.3 Rack #175

905 Sheehy Drive <sup>D<sup>sh</sup></sup>  
3/22/00

## ANALYTICAL RESULTS

Water Safety Classification: No Coliform bacteria were detected. Therefore, the water supply, at the time of sampling, meets the EPA and DEP drinking water standards for this parameter.

<u>Parameter</u>	<u>MCL</u>	<u>Result</u>
Total Coliform Bacteria, counts/100 ml	< 1	< 1
coliform bacteria, counts/100 ml		< 1
Total Chlorine, mg/l as Cl		0.4

D. Lebo  
3/22/00

Results which are outside the "Maximum Contaminant Level" (MCL) established under the "Safe Drinking Water Act" are marked with asterisks (\*\*).

## Symbol key:

TNTC - Too numerous to count (> 200)

< - Less than

mg/l - milligrams/liter

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ANALYTICAL LABORATORIES, INC.  
P.O. Box 319  
Chalfont, PA 18914  
(215) 723-6466

## SAMPLE ANALYSIS REPORT

Customer: Argus Research Inc.  
905 Sheehy Dr., Building A  
Horsham, PA 19044  
Attn. Dena Lebo  
Attn: 215-443-8710  
FAX : 215-443-8587

Sample Number : 2478-00D  
Date Sampled : 03/10/00  
Time Sampled : 1415  
Date Received : 03/10/00  
Sampled By : RW

Sample source: Chem. Lab II

905 Sheehy Drive @ 3/22/00

## ANALYTICAL RESULTS

Water Safety Classification: No Coliform bacteria were detected. Therefore, the water supply, at the time of sampling, meets the EPA and DEP drinking water standards for this parameter.

<u>Parameter</u>	<u>MCL</u>	<u>Result</u>
Total Coliform Bacteria, counts/100 ml	< 1	< 1
Coliform bacteria, counts/100 ml	< 1	< 1
Total Chlorine, mg/l as Cl		< 0.1

D. Lebo  
3/22/00

Results which are outside the "Maximum Contaminant Level" (MCL) established under the "Safe Drinking Water Act" are marked with asterisks (\*\*).

## Symbol key:

TNTC - Too numerous to count (> 200)

< - Less than

mg/l - milligrams/liter

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APPENDIX F  
ANALYTICAL REPORT

**HORMONE, THYROID AND NEUROHISTOLOGICAL EFFECTS OF ORAL (DRINKING  
WATER) EXPOSURE TO AMMONIUM PERCHLORATE IN PREGNANT AND LACTATING  
RATS AND IN FETUSES AND NURSING PUPS EXPOSED TO AMMONIUM PERCHLORATE  
DURING GESTATION OR VIA MATERNAL MILK  
PROTOCOL 1416-003**

**CONCENTRATION ANALYSES REPORT**

**SUBMITTED TO:**  
Raymond G. York, Ph.D., D.A.B.T.  
Argus Research Laboratories, Inc.  
905 Sheehy Drive, Building A  
Horsham, Pennsylvania 19044

**SUBMITTED BY:**  
**Latha Narayanan**

**MANTECH GEO-CENTERS JOINT VENTURE  
P.O. BOX 31009  
DAYTON OH 45437-0009**

**David Mattie, Ph.D., D.A.B.T.**

**AFRL/HEST, Bldg 79  
2856 G Street  
Wright-Patterson AFB, OH 45433-7400**

## Introduction

Ammonium perchlorate is an oxidizer that has been used as a component of solid rocket fuel (EPA, 1998). Perchlorate, the dissociated ion of ammonium perchlorate, has recently been recognized as a persistent and pervasive contaminant of water supplies in a number of major metropolitan areas (personal communication, D. Rogers). Ammonium perchlorate is a white, crystalline salt that readily dissociates in water. It was previously shown to be stable in reagent water at room temperature for at least 109 days (Tsui, Mattie and Narayanan, 1998).

## Methods

**Compliance Statement:** The analyses in this report entitled "Concentration Analyses Report" were conducted in the spirit of the Environmental Protection Agency's Good Laboratory Practices Standards, 40 CFR 792.

**Sample Collection:** Perchlorate formulations were prepared by Argus Research Lab, Inc. Triplicate samples (2 mL each) were taken from each of the prepared formulations (including stock and carrier) on the first and last days of preparation. Two samples were shipped to AFRL/HEST by overnight delivery and the remaining samples were retained at the testing laboratory as backup samples. Samples were kept refrigerated at 4° C prior to analysis for perchlorate. The target doses of perchlorate were 0 (Carrier), 0.01, 0.1, 1.0, or 30.0 mg/kg-day.

**Perchlorate Analysis:** Test Materials, reagents, calibration standards and analytical methods were performed according to the procedure of Tsui, Mattie and Narayanan (1998).

**Statistical Analysis:** Linearity of the standard curve was verified by testing for correlation using the subroutine in Microsoft Excell.

## Results

Table 1 shows the perchlorate analysis for samples taken on the first day of solution preparation. Figure 1 shows the standard curve used to determine the perchlorate values. Table 2 shows the perchlorate analysis for samples taken on the last day of solution preparation. Figure 2 shows the standard curve used to determine the perchlorate values for the last day of formulation preparation. Values for all samples tested show good agreement between the target dose and the actual perchlorate value. All measured values were within 5% (usually less) of the target values.

### **References**

EPA. (1998). Perchlorate environmental contamination: toxicological review and risk characterization based on emerging information. External review draft, December 31, 1998. National Center for Environmental Assessment, Washington, D.C. NCEA-1-0503.

Rogers, Daniel Lt Col. (2000). Personal communication. 314<sup>TH</sup> AW/JA, Little Rock AFB, Arkansas.

Tsui, D.T., Mattie, D.R., and Narayanan, L. (1998) Stability and concentration verification of ammonium perchlorate dosing solutions. United States Air Force, Armstrong Laboratory, AFRL-HE-WP-TR-1998-0068.

**Table 1. Perchlorate Analysis for Samples Take on the First Day of Preparation.**

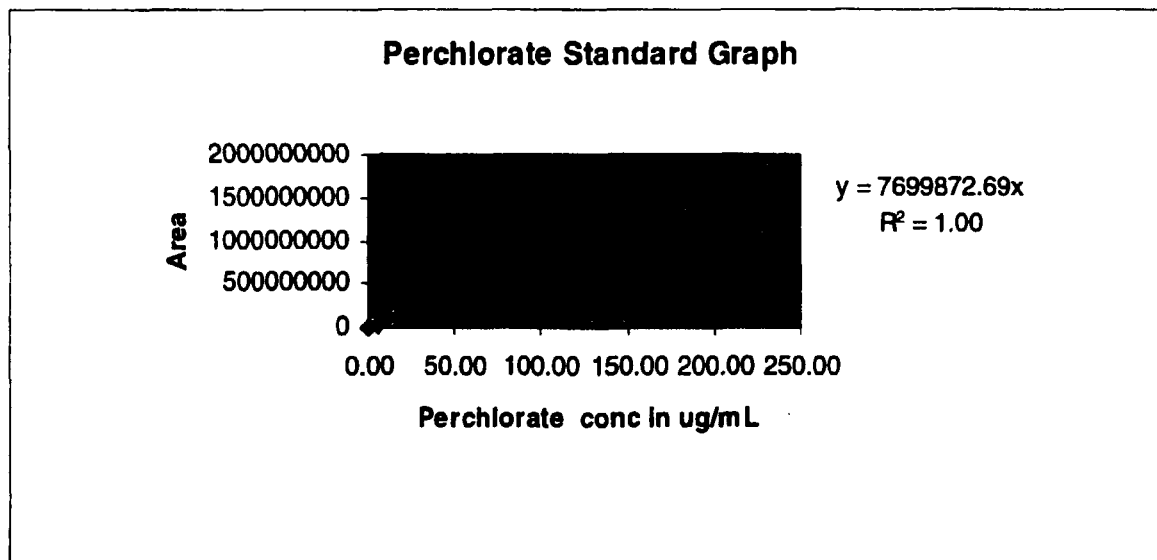
Batch #	Perchlorate Analysis	Area1 Generated on 12/30/99	Area2 Generated on 12/30/99	Mean Area-BKG Generated on 12/30/99	Perchlorate conc in mcg/mL	Dilution Factor	Perchlorate conc in mcg/mL	Perchlorate conc in mg/mL
	Dose Samples From Argus Lab							
1416-003	A - 0 mcg/mL	0	0	0	0	1	0	0.0000
1416-003	B - 0.0658 mcg/mL	506012	512618	509315	0.066145899	1	0.066145899	0.0001
1416-003	C - 0.658 mcg/mL	5060686	5051405	5056045.5	0.656640142	1	0.656640142	0.0007
1416-003	D - 6.58 mcg/mL	51856141	50091175	50973658	6.620065039	1	6.620065039	0.0066
1416-003	E - 197.27 mcg/mL	739020304	782754399	760887351.5	98.81817299	2	197.636346	0.1976
1416-003	F - 10 mg/mL	494488515	494125706	494307110.5	64.19679005	156	10014.69925	10.0147
	HClO4 20ug/mL-Control	156566786	156566786	156566786	20.33368502			
	A- 0.00 mcg/mL	0	0	0	0.000			
	Control+Spike 20.00 mcg/mL	156574444	156574444	156574444	20.33467959			

**Figure 1. Standard Curve for Perchlorate Analysis for Samples Take on the First Day of Preparation.**

Perchlorate Conc in Mean Area-BKG  
ug/mL

Generated on  
12/30/99

0.00	0
5.00	38953630
10.00	73702666
20.0	156566786
50.0	417379406
75.0	640215223
200	1508252819



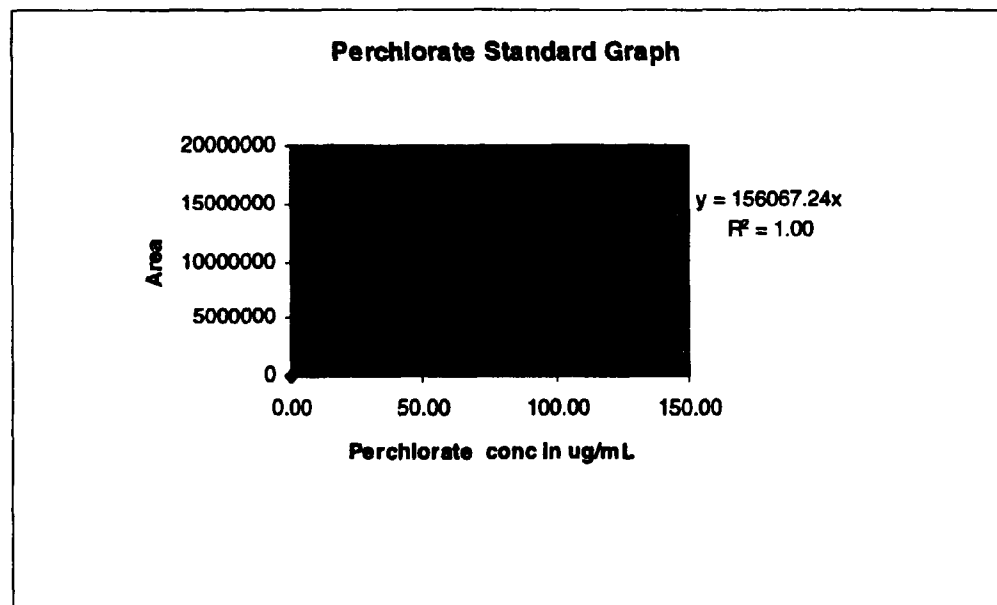


**Table 2. Perchlorate Analysis for Samples Taken on the Last Day of Preparation.**

Batch #	Perchlorate Analysis	Area1 Generated on 03/07/00	Area2 Generated on 03/07/00	Mean Area-BKG Generated on 03/07/00	Perchlorate conc in ng/mL	Dilution Factor	Perchlorate conc in ng/mL	Perchlorate conc in mcg/mL	Perchlorate conc in mg/mL
	Dose Samples From Argus Lab								
1416-003	A - 0 mcg/mL	0	0	0	0.00	1	0	0.0000	0.0000
1416-003	B - 0.0665 mcg/mL	10473272	10456260	10464766	67.05	1	67.0529318	0.0671	0.0001
1416-003	C - 0.623 mcg/mL	965968	984906	975437	6.25	100	625.0107326	0.6250	0.0006
1416-003	D - 6.78 mcg/mL	1025644	1136324	1080984	6.93	1000	6926.39916	6.9264	0.0069
1416-003	E - 218.50 mcg/mL	11604072	11315516	11459794	73.43	2975	218449.9909	218.4500	0.2184
1416-003	F - 10 mg/mL	1033446	1047444	1040445	6.67	1500000	9999968.603	9999.9686	10.0000
	HClO4 10 mcg/mL- Standard	1556940	1556940	1556940	9.98				
	A- 0.00 mcg/mL	0	0	0	0.000				
	Control+Spike 10.00 mcg/mL	1563384	1563384	1563384	10.02				

**Figure 2. Standard Curve for Perchlorate Analysis for Samples Taken on the Last Day of Preparation.**

Perchlorate Conc in ng/mL	Mean Area-BKG
	Generated on 03/07/00
0.00	0
5.00	995180
10.00	1666842
20.00	2886462
50.00	8204100
100.00	15431972



APPENDIX G  
HISTORICAL CONTROL DATA

SUMMARY OF REPRODUCTIVE INDICES  
*Crl:CD(SD)IGS BR* RATS  
 DAY 21 C-SECTION

PERIOD                      JUNE 1998 - SEPTEMBER 1999

NUMBER OF STUDIES                      13

NUMBER OF RATS:

TESTED                      252

PREGNANT                      235

FOUND DEAD                      1

ABORTED                      0

DELIVERED                      0

NUMBER OF RATS PREGNANT AT  
CAESAREAN-SECTIONING                      234

NUMBER OF RATS WITH SINGLE  
CONCEPTUS LITTER:

LIVE                      0

RESORBED                      0

ABORTED                      0

	MEAN or %	RANGE/STUDY MEAN or %
% PREGNANT	93.4	(87.5-100)
AVERAGE # CORPORA LUTEA	17.6	(16.4-19.1)
AVERAGE # IMPLANTATIONS	14.9	(14.0-16.3)
AVERAGE LITTER SIZE		
AVERAGE # LIVE FETUSES	14.5	(13.6-15.9)
AVERAGE # DEAD FETUSES	0.0	--
AVERAGE # RESORPTIONS	0.5	(0.1-1.4)
AVERAGE # EARLY RESORPTIONS	0.5	(0.1-1.4)
AVERAGE # LATE RESORPTIONS	0.0	(0-0.1)

SUMMARY OF REPRODUCTIVE INDICES  
*Crit:CD(SD)/GS BR RATS*  
 DAY 21 C-SECTION

	MEAN or %	RANGE/STUDY MEAN or %
AVERAGE % DAMS WITH ANY RESORPTIONS	39.3	(12.5-71.4)
AVERAGE % DAMS WITH ALL CONCEPTUSES RESORBED	0.0	--
AVERAGE % DAMS WITH ONE OR MORE LIVE FETUSES	100.0	--
AVERAGE SEX RATIO, (% MALES/LITTER)	49.4	(43.0-57.0)
AVERAGE FETAL BODY WEIGHT (G)	5.28	(5.10-5.48)
AVERAGE FOR MALES (G)	5.40	(5.15-5.63)
AVERAGE FOR FEMALES (G)	5.12	(4.92-5.29)
AVERAGE % DEAD OR RESORBED CONCEPTUSES/LITTER	3.3	(0.8-8.8)

**SUMMARY OF MATERNAL NECROPSY OBSERVATIONS**  
*Crl:CD(SD)IGS BR* RATS - DAY 21 C-SECTION

PERIOD      JUNE 1998 - SEPTEMBER 1999

# STUDIES	13
# RATS TESTED	252
# RATS PREGNANT	235
# RATS DIED	1
# RATS ABORTED	0
# RATS DELIVERED	0
# RATS WITH 100% RESORPTION	0

OBSERVATIONS		RANGE / STUDY			
		N	%	N	%
LIVER					
	Left lateral lobe, tan area	1	0.40	0-1	(0-4.0)
UTERUS					
	Moderate hydrometra	1	0.40	0-1	(0-4.2)
INGUINAL AREA					
	Subcutaneous, tan mass on right side	1	0.40	0-1	(0-4.5)

**SUMMARY OF FETAL GROSS EXTERNAL ALTERATIONS**  
*Crit:CD(SD)/GS BR RATS - DAY 21 C-SECTION*

PERIOD                      JUNE 1998 - SEPTEMBER 1999

# STUDIES INCLUDED	13
# LITTERS EXAMINED	234
# LIVE FETUSES EXAMINED	3383

ALTERATION			N	%	RANGE	/STUDY
					N	%
EYE(S)						
	Eye bulges depressed	L	1	0.43	0-1	(0-4.2)
		F	1	0.03	0-1	(0-0.3)
JAWS						
	Micrognathia	L	1	0.43	0-1	(0-4.2)
		F	1	0.03	0-1	(0-0.3)
HINDPAW						
	Extra digit present	L	1	0.43	0-1	(0-4.5)
		F	1	0.03	0-1	(0-0.3)
TAIL						
	Threadlike	L	1	0.43	0-1	(0-4.3)
		F	1	0.03	0-1	(0-0.3)

L: LITTER INCIDENCE  
 F: FETAL INCIDENCE

SUMMARY OF FETAL SOFT TISSUE ALTERATIONS  
*Cr:CD(SD)IGS BR RATS*  
 DAY 21 C-SECTION

PERIOD JUNE 1998 - SEPTEMBER 1999  
 # STUDIES INCLUDED 8  
 # LITTERS EXAMINED 180  
 # FETUSES EXAMINED 1245

	ALTERATION		N	%	RANGE/STUDY	
					N	%
BRAIN						
	Dilation of lateral ventricles	L	2	1.11	0-2	(0-8.3)
		F	2	0.16	0-2	(0-1.2)
HEART						
	Septal defect	L	1	0.56	0-1	(0-4.2)
		F	1	0.08	0-1	(0-0.6)
VESSELS						
	Umbilical artery, descends	L	3	1.67	0-2	(0-9.1)
	to left of urinary bladder	F	3	0.24	0-2	(0-1.2)
	Innominate artery, absent	L	2	1.11	0-2	(0-8.3)
		F	2	0.16	0-2	(0-1.2)
	Aorta passes dorsal to the	L	1	0.56	0-1	(0-4.2)
	trachea and esophagus	F	1	0.08	0-1	(0-0.6)
	Left carotid rises to the	L	1	0.56	0-1	(0-4.2)
	right of the right carotid	F	1	0.08	0-1	(0-0.6)
	Right carotid rises to the					
	right of the right sub-	L	1	0.56	0-1	(0-4.2)
	clavian	F	1	0.08	0-1	(0-0.6)
	Pulmonary artery, small	L	1	0.56	0-1	(0-4.2)
		F	1	0.08	0-1	(0-0.6)
	Semilunar valve, small	L	1	0.56	0-1	(0-4.2)
		F	1	0.08	0-1	(0-0.6)
	Ductus arteriosus attached	L	1	0.56	0-1	(0-4.2)
	to the left subclavian	F	1	0.08	0-1	(0-0.6)
	Great vessels, transposed	L	2	1.11	0-1	(0-4.3)
		F	2	0.16	0-1	(0-0.7)
LUNGS						
	Apical and cardiac lobes,	L	1	0.56	0-1	(0-4.2)
	absent	F	1	0.08	0-1	(0-0.6)
KIDNEY(S)						
	Pelvis, slight dilation	L	1	0.56	0-1	(0-4.5)
		F	1	0.08	0-1	(0-0.7)
	Pelvis, marked dilation	L	1	0.56	0-1	(0-4.5)
		F	1	0.08	0-1	(0-0.7)

L: LITTER INCIDENCE  
 F: FETAL INCIDENCE



**SUMMARY OF FETAL SKELETAL ALTERATIONS**  
*Crl:CD(SD)IGS BR RATS - DAY 21 C-SECTION*

PERIOD	JUNE 1998 - SEPTEMBER 1999
# STUDIES INCLUDED	8
# LITTERS EXAMINED	180
# FETUSES EXAMINED	1332

			RANGE / STUDY	
ALTERATION	N	%	N	%
SKULL				
Eye socket: small	L	1	0.56	0-1 (0-4.2)
	F	1	0.08	0-1 (0-0.6)
Mandibles: short	L	1	0.56	0-1 (0-4.2)
	F	1	0.08	0-1 (0-0.6)
VERTEBRAE				
Thoracic: Centrum, bifid	L	4	2.22	0-1 (0-4.8)
	F	4	0.30	0-1 (0-0.6)
: Centrum, fused to arch	L	1	0.56	0-1 (0-4.8)
	F	1	0.08	0-1 (0-0.6)
: 4 present	L	1	0.56	0-1 (0-4.8)
	F	1	0.08	0-1 (0-0.6)
Lumbar: Fused	L	2	1.11	0-1 (0-4.8)
	F	2	0.15	0-1 (0-0.6)
: 8 present	L	1	0.56	0-1 (0-4.8)
	F	1	0.08	0-1 (0-0.6)
: Centrum, fused to arches	L	1	0.56	0-1 (0-4.8)
	F	1	0.08	0-1 (0-0.6)
RIBS				
Cervical Rib(s) present	L	12	6.67	0-5 (0-20.8)
	F	14	1.05	0-6 (0-3.5)
One or more, wavy	L	6	3.33	0-2 (0-9.5)
	F	8	0.60	0-3 (0-1.8)
One or more, incompletely ossified (hypoplastic), or not ossified	L	2	1.11	0-2 (0-9.1)
	F	3	0.22	0-3 (0-1.8)
Fused	L	1	0.56	0-1 (0-4.2)
	F	1	0.08	0-1 (0-0.6)
4 present	L	1	0.56	0-1 (0-4.8)
	F	1	0.08	0-1 (0-0.6)

L: LITTER INCIDENCE  
F: FETAL INCIDENCE

**SUMMARY OF FETAL SKELETAL ALTERATIONS**  
*Cr:CD(SD)IGS BR RATS - DAY 21 C-SECTION*

ALTERATION		N	%	RANGE / STUDY	
				N	%
MANUBRIUM					
Duplicated	L	1	0.56	0-1	(0-4.5)
	F	1	0.08	0-1	(0-0.6)
STERNEBRAE					
One or more incompletely ossified or not ossified	L	4	2.22	0-2	(0-9.1)
	F	4	0.30	0-2	(0-1.2)
Asymmetric	L	2	1.11	0-1	(0-4.5)
	F	2	0.15	0-1	(0-0.6)
Duplicated	L	1	0.56	0-1	(0-4.5)
	F	1	0.08	0-1	(0-0.6)
XIPHOID					
Duplicated	L	1	0.56	0-1	(0-4.5)
	F	1	0.08	0-1	(0-0.6)
HINDLIMB					
Extra digit present	L	1	0.56	0-1	(0-4.5)
	F	1	0.08	0-1	(0-0.6)
Femur, bent	L	1	0.56	0-1	(0-4.8)
	F	1	0.08	0-1	(0-0.6)

L: LITTER INCIDENCE  
F: FETAL INCIDENCE

SUMMARY OF FETAL OSSIFICATION SITES  
 SKELETAL AVERAGES  
*Crl:CD(SD)IGS BR* RATS  
 DAY 21 C-SECTION

PERIOD: JUNE 1998 - SEPTEMBER 1999  
 # STUDIES INCLUDED 8  
 # LITTERS EXAMINED 180  
 # FETUSES EXAMINED 1331

SKELETAL AVERAGES	FETUS/LITTER	
	MEAN	RANGE/STUDY
HYOID	0.99	(0.96-1.00)
VERTEBRAE		
CERVICAL	7.00	--
THORACIC	13.07	(13.03-13.14)
LUMBAR	5.92	(5.85-5.97)
SACRAL	3.00	--
CAUDAL	7.44	(7.11-7.63)
RIBS (pairs)	13.05	(13.02-13.12)
STERNUM		
MANUBRIUM	1.00	--
STERNAL CENTERS	3.99	(3.98-4.00)
XIPHOID	1.00	--
FOREPAWS (Calculated as average per limb)		
CARPALS	0.00	--
METACARPALS	4.00	(3.99-4.00)
DIGITS	5.00	--
PHALANGES	8.28	(8.04-8.52)
HINDPAWS (Calculated as average per limb)		
TARSALS	0.02	(0-0.07)
METATARSALS	4.80	(4.73-4.87)
DIGITS	5.00	--
PHALANGES	6.21	(5.81-6.54)

APPENDIX H  
QUALITY ASSURANCE UNIT FINAL REPORT STATEMENT



Argus Research Laboratories, Inc.  
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Horsham, PA 19044  
Telephone: (215) 443-8710  
Telefax: (215) 443-8587

## QUALITY ASSURANCE UNIT FINAL REPORT STATEMENT

Study Director: Raymond G. York, Ph.D., DABT

Executive Director of Research: Mildred S. Christian, Ph.D., Fellow, ATS

Protocol 1416-003: Oral (Drinking Water) Developmental Toxicity Study of  
Ammonium Perchlorate in Rats

The draft protocol for this study was audited for adherence to U.S. Environmental Protection Agency (EPA TSCA) Good Laboratory Practice Standards on 27 DEC 99 to 28 DEC 99.

Critical phases of this study were inspected three times; study information and raw data were audited twice (see tables 1 and 2 for dates and phases/data).

The draft final report and the raw data for this study were compared and audited for accuracy, for adherence to protocol requirements, and for adherence to U.S. Environmental Protection Agency (EPA TSCA) Good Laboratory Practice Standards between 17 MAY 00 and 01 JUN 00, and for finalization on 04 AUG 00.

This study was conducted according to U.S. Environmental Protection Agency (EPA TSCA) Good Laboratory Practice Standards.

*Nancy J. Gongliwski 4 Aug 00*  
Nancy J. Gongliwski      Date  
Quality Assurance Manager

*Nancy J. Gongliwski 4 Aug 00*  
for Lisa A. Zaborowski, B.S.      Date  
Senior Quality Assurance Associate  
and Principal Auditor

TABLE 1  
CRITICAL PHASES INSPECTED

Test Substance Preparation

Date of inspection: 02 FEB 00

Date results reported to the Study Director and Management: 11 FEB 00

Cohabitation

Date of inspection: 16 FEB 00

Date results reported to the Study Director and Management: 23 FEB 00

Caesarean-Sectioning

Date of inspection: 07 MAR 00

Date results reported to the Study Director and Management: 20 MAR 00

## TABLE 2

## RAW DATA AUDIT(S)

The following study information and raw data were audited from 14 MAY 00 to 20 MAY 00:

- Protocol.
- Protocol amendments.
- List of personnel and computer operator codes.
- Error codes and codes for clinical sign observations.
- Animal receipt, randomization, physical examination and acclimation.
- In-life transaction record.
- Feed consumption.
- Water consumption.
- Cohabitation.
- Caesarean-sectioning.
- Maternal gross observations.
- Fetal gross observations.
- Fetal fixative assignment.
- Fetal visceral examination.
- Fetal skeletal examination.
- Necropsy.
- Organ weights.
- Tissue packing lists.
- Male breeder colony records.
- General comments.
- Study maintenance records.
- Temperature and relative humidity reports.
- Feed, water and bedding analyses.
- Edit requests.
- Deviations.
- Data review pages.
- Balance accuracy verification.

The results of this audit were reported to the Study Director and Management on 22 MAY 00.

The following study information and raw data were audited on 21 MAY 00 to 30 MAY 00:

Test substance receipt, preparation and use.  
Test substance packing lists.

The results of this audit were reported to the Study Director and Management on 30 MAY 00.